Depression and HIV/AIDS: adapting and piloting group interpersonal therapy for treatment of depressive symptoms for people living with HIV/AIDS in Northwest Ethiopia

Biksegn Asrat

Student Number: ASRBIK001

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Supervisor: A/Professor Marguerite Schneider

Co-supervisors: Professor Crick Lund and A/Professor Fentie Ambaw

Declarations

I, Biksegn Asrat, present this thesis in fulfilment of the requirements for the degree of Doctor of Philosophy (PhD) in the Department of Psychiatry and Mental Health, Faculty of Health Sciences, University of Cape Town. I hereby declare that this thesis is my original work and that neither the whole work nor any part of it has been, is being, or will be submitted for another degree in this or any other university. Ethical approval was obtained from Ethics Research Committee of the Faculty of Health Sciences at the University of Cape Town (HREC REF: 653/2018) (see Appendix A) and Institutional Review Board of College of Medicine and Health Sciences, Bahir Dar University (Reference No. 007/2018) (see Appendix B).

I confirm that I have been granted permission by the University of Cape Town's Doctoral Degrees Board to include the following publications in my PhD thesis, and where co-authorships are involved, my co-authors have agreed that I may include the publications:

1. Asrat B, Schneider M, Ambaw F and Lund C. Effectiveness of psychological treatments for depressive symptoms among people living with HIV/AIDS in low- and middle-income countries: A systematic review and meta-analysis. *Journal of Affect Disorders; 2020; 270 (2020):174-187*. (Chapter 2).
2. Asrat B, Lund C, Ambaw F, Garman CE and Schneider M. Major depressive disorder and its association with adherence to antiretroviral therapy and quality of life: cross-sectional survey of people living with HIV/AIDS in Northwest Ethiopia. *BMC Psychiatry; 2020; 20(462):1-13*. (Chapter 3).
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Approval is obtained from Doctoral Degrees Board (DDB) for inclusion of published papers in the present thesis (See Appendix C). English version questionnaires, an interview guide and checklists are available in Appendix D[1].

[1] **All Amharic translations are available on request from the author.**

This thesis/dissertation has been submitted to the Turnitin module and I confirm that my supervisor has seen my report and any concerns revealed by such have been resolved with my supervisor.

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Abstract

Background

Being diagnosed with HIV/AIDS and commencement of lifelong antiretroviral therapy (ART) with the requirement of high adherence can exacerbate or trigger depressive disorders. Prevalence of major depression is substantially higher in people living with HIV/AIDS (PLWHA) than those in the general population. More than 50% of PLWHA are likely to meet one or more criteria for depression in their lifetime. However, access to interventions for depressive disorders remains limited in Low- and Middle-Income Countries (LMICs) where more than 90% of people with depressive disorders are not receiving formal treatment. The role of evidence-based psychological treatments has been fundamental in reducing the huge treatment gap in LMICs. Although brief, flexible and effective psychological treatments are emerging, issues in relation to their acceptability, feasibility and effectiveness in HIV populations remain unexplored. Therefore, this thesis aimed to adapt and pilot group interpersonal therapy (IPT) for treatment of depressive symptoms including its acceptability and feasibility for PLWHA.

This thesis has been the first that attempted to adapt and pilot group IPT for treatment of depression in the HIV population in Ethiopia. The findings of this thesis can serve as a baseline for researchers interested in adapting or developing psychological treatments in the HIV population in Ethiopia. The findings contribute information on the process used in examining acceptability and feasibility of psychological interventions which provides indications for conducting future trials to test the effectiveness of group IPT.

Methods

First, a systematic review and meta-analysis of randomised controlled trials was conducted to identify the most effective psychological treatments for depressive symptoms for PLWHA in LMICs. Second, a survey of major depressive disorder (MDD) was conducted among PLWHA who were attending ART follow-up appointments at the Felege-Hiwot Referral Hospital (FHRH) in Northwest Ethiopia. The survey served as a baseline to identify cases for piloting of group IPT and helped to identify areas for intervention. Third, the intervention areas were further explored among stakeholders from the ART clinic including PLWHA and this was followed by a stepwise adaptation of the group IPT manual. Furthermore, a formative qualitative study was conducted to examine explanatory models of depression and to explore acceptable contexts for implementation of group IPT. A total of three focus groups were conducted with purposively selected case managers, adherence supporters and service users at the ART clinic. The qualitative data were

analysed based on a framework approach using predefined thematic concepts. Fourth, a pilot study of the group IPT intervention was conducted among PLWHA to evaluate the acceptability and feasibility of peer-administered group IPT for treatment of depressive symptoms for PLWHA in Ethiopia. A single-arm, pre-post, peer-administered, group IPT interventional study was conducted with 31 consecutively recruited participants. The participants were assigned to four IPT groups for the intervention. A post-intervention evaluation of depressive symptoms, perceived social support (PSS), functional disability and quality of life (QoL) was conducted using the same instruments used at the baseline. No control group was included in this pilot study.

Results

The findings of the systematic review and meta-analysis revealed that trials that used IPT have shown good effectiveness in treating depressive symptoms of PLWHA in LMICs. The baseline study found 32.5% prevalence of MDD among randomly selected PLWHA (N=393). MDD was positively associated with reduced adherence to ART, functional disability and negatively associated with overall QoL. Overall findings of the baseline and the qualitative study indicated that psychosocial problems are the most important factors that need intervention for depression for PLWHA. The main findings in relation to the adaptation of the WHO group IPT were: i) an IPT group that contains five to ten people was perceived to be acceptable and mixed gender groups were recommended; ii) sessions were recommended to be conducted in private rooms for 1.5 to 2 hours, and on a weekly basis. Findings of the pilot study indicated that depression scores reduced significantly between baseline and post-intervention (mean difference (MD)=9.92; t=-7.82; p<0.001). The mean PSS scores (MD=0.79; t=2.84; p=0.009) and the mean QoL scores (MD=0.39, t=4.58, p<0.001) improved significantly between baseline and post-intervention.

All the IPT intervention areas (life change, disagreement, grief and loneliness) were found to be applicable to and important areas associated with depression in PLWHA in Ethiopia. Most importantly, disagreement within a family and life change due to HIV/AIDS, such as sickness and separation were faced by almost all PLWHA included in the study, followed by loneliness or social isolation as result of HIV stigma, and grief due to loss of loved ones including a spouse, a child, a mother or a father.

Overall evaluation of the pilot indicated that the procedures and outcomes of group based IPT were perceived as acceptable. Participants of the intervention gained benefits in resolving psychosocial problems and reported high satisfaction with counsellors and intervention setting.

The eight weekly sessions that lasted around two hours were acceptable; however, additional sessions were recommended by some counsellors until everyone recovers from depression.

Conclusion

The overall findings of this thesis suggested that group IPT was found to be acceptable and feasible for PLWHA in Ethiopia. Future studies should focus on examining its effectiveness for treating depressive disorders among PLWHA in Ethiopia.

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List of abbreviations

Abbreviation	Definition
ART	Antiretroviral Therapy
CBT	Cognitive Behavioural Therapy
CI	Confidence Interval
FHRH	Felege-Hiwot Referral Hospital
FMOH	Federal Ministry of Health
GSP	Group Support Psychotherapy
HEW	Health Extension Worker
IPT	Interpersonal Therapy
IPV	Intimate Partner Violence
LMICS	Low- and Middle-income countries
MDD	Major Depressive Disorder
mhGAP	Mental Health Gap Action Programme
MINI	Mini-International Neuropsychiatric Interview
PIPFLA	Participatory and Iterative Process Framework for Language Adaptation
PLWHA	People Living With HIV/AIDS
PSS	Perceived Social Support
PST	Problem-Solving Therapy
QoL	Quality of Life
SMD	Standard Mean Difference
SSA	sub-Sahara Africa
USA	United States of America
WHO	World Health Organization
WHODAS	WHO Disability Assessment Schedule
WHOQOL-HIV	World Health Organization Quality of Life-HIV version
YLD	Years Lived with Disability

Chapter 1. Introduction

This chapter reviews the global and local literature pertaining to the burden of depression and its health-related outcomes in people living with HIV/AIDS (PLWHA). It also summarises the current evidence on the treatment gap and the role of psychological treatments in reducing the burden of depression in low- and middle-income countries (LMICs), particularly in Ethiopia. The rationale for this thesis and research objectives are then described. Finally, the setting in which the present research took place is briefly described.

1.1. Burden of depression

Depressive disorders are the most common mental health problems affecting over 300 million people globally, accounting for 4.4% of the world's population (1, 2). The total number of people with depressive disorders increased by 18.4% between 2005 and 2015 (1). Depressive disorders are the leading cause of the mental health-related disease burden (3) and contribute to more than 800,000 suicide deaths per year globally (1). According to a study on the global burden of diseases in 2017, of all diseases and injuries, depressive disorders were the third leading cause of years lived with disability (YLD) (4). The World Health Organization (WHO) report on burden of mental disorders shows that depressive disorders accounted for 50 million YLD globally in 2015 and more than 80% of the burden of depressive disorders occurred in LMICs, with more than seven million YLD occurring in Africa (1). Depressive disorders remain one of the barriers to achieving the sustainable development goals (5) and are associated with a high risk of all causes of mortality, including cardiovascular death and stroke (6). Reducing suicide by 10% in 2020 was one of the target goals of the WHO mental health action plan (7). Unfortunately, to date, depressive disorders continue to contribute to more than 68% of all suicide deaths (3). In addition, socio-economic adversities such as unemployment and poverty are also associated with depressive disorders (6, 8).

In addition to shared risk factors between depression and HIV/AIDS (e.g. poverty), being diagnosed with HIV/AIDS, a life-threatening chronic illness necessitating lifelong antiretroviral therapy (ART) with a need for high adherence, can exacerbate or trigger depressive disorders. In association with declining death rates from HIV, depressive disorders are becoming more prevalent among PLWHA (9). More than 50% of PLWHA are likely to meet one or more criteria for depression in their lifetime (10, 11). Prevalence of major depression is nearly two times higher among PLWHA than those in the general population (12, 13). In low-income countries, the

prevalence of depressive disorders using diagnostic instruments can be as high as 63% among PLWHA (14). A meta-analysis of 74 observational studies found a 50.8% pooled prevalence of depression among PLWHA in China (10). A meta-analysis of studies from Africa found a 15.3% pooled prevalence of major depressive disorder (MDD) using a diagnostic interview (15). Table 1 presents a range of systematic reviews and meta-analysis studies conducted in LMICs and their findings on the prevalence of depression among PLWHA. Several studies have reported a range of prevalence estimates for depression, which vary from 7.3% to 76.7% among PLWHA in Ethiopia (16, 17). A meta-analysis of studies conducted in Ethiopia has shown a 36.7% pooled prevalence of probable depression among PLWHA (18). However, the heterogeneity of studies in terms of measurement variation and study design limits our ability to draw conclusions on the prevalence of depressive disorders among PLWHA in Ethiopia. In addition, the timing of the depression assessment following receiving the diagnosis of HIV/AIDS influences the prevalence of depressive disorders (14). Measuring depression immediately after HIV diagnosis can artificially inflate estimates, where adjustment reactions may be mislabelled as depression.

There is a large body of evidence that depression can lead to poor clinical outcomes and a high risk of mortality among PLWHA (6). A prospective cohort epidemiological study from the United States of America (USA) found that women with chronic depression had two times greater risk of mortality than women with limited or no depressive symptoms (19). A cohort study of seropositive men in San Francisco, USA demonstrated that men with depressive symptoms had 1.7 times greater risk of mortality than men without depressive symptoms (20). PLWHA who had comorbid mental illness including depression had three times increased risk of dying from all causes of death compared to those who had no history of mental illness in South Africa (21). Evidence shows that there is a relationship between depression and altered immunity, although the mechanism of association remains unclear (19). However, biological studies argue that a low lymphocyte response to mitogens occurs in people with depression and leads to low immune functioning and poor recovery (22). In turn, low immunological functioning hastens advanced stages of disease and mortality (22).

Several studies provide a biological explanation to the relationship between depression and poor outcome of HIV/AIDS; however, vegetative symptoms of depression such as poor food intake, weight loss and insomnia can also contribute to the poor outcome of HIV/AIDS. For example, nutritional deficiency due to poor appetite and insomnia could also predict a poor prognosis of HIV/AIDS (23). Despite existing evidence, more interventional research is needed to manage depression and improve the outcomes of HIV/AIDS.

Table 1. Prevalence of depression among people living with HIV/AIDS in range of systematic review and meta-analysis studies in low- and middle-income countries.

N	Author & Year	Setting	Tool	Sample	Pooled prevalence	Predictors
1	Ayano G, et al 2018 (24)	East Africa	Not described	19 articles	38% pooled prevalence of depression. It ranges from 12% to 46% depending on measurement.	Having opportunistic infection, perceived stigma, hospitalisation in the past month, food insecurity, frequency of missed clinic visits, older age, low income, urban residence and being government employee
2	Bernard C, et al, 2017 (25)	sub-Saharan Africa	MINI, DSM-IV, PHQ-9	66 articles	9% to 32%	Low socio-economy, female sex and low CD4
3	Lofgren SM, 202 (15)	sub-Sahara Africa	Diagnostic interview and screening tools	70 articles	15.3% prevalence of major depression and 25.5% prevalence of probable depression was reported	Not described
4	Nakimuli-Mpungu E, et al, 2012 (26)	sub-Sahara Africa	12 studies used validated instruments	23 articles	31.2% prevalence of mild to moderate depression and 18% major depression	Adherence to ART medication
5	Patel P, et al 2018 (27)	Low- and middle-income countries	Kessler (6 and 10), HSCL, PHQ-9, CES-D, Edinburgh Post-Natal Depression Scale (EPDS)	141 articles on non-communicable diseases including depression	24.4% (95%CI: 12.5-42.1) pooled prevalence of depression	Not described
6	Amare T, et al, 2018 (18)	Ethiopia	CES-D, PHQ-9, Kessler-6, HADS, BDI	13 articles	36.7% pooled prevalence of depression was reported	Age, living alone, poor adherence, poor social support, clinical stages, stigma, no income
7	Wang T, et al, 2018 (10)	China	SCL-90, CES-D-20, Zung Self-Rating Depression Scale (Zung SDS)	74 articles	50.8% (95% CI: 46.0–55.5%) pooled prevalence of depression was reported.	Not described

Key: CES-D – Center for Epidemiological Studies Depression scale, DSM-IV – Diagnostic Statistical Manual fourth edition, HADS – Hospital Anxiety and Depression Scale, PLWHA – People Living With HIV/AIDS, MINI – Mini International Neuropsychiatric Interview, PHQ-9 – Patient Health Questionnaire

1.2. Risk factors for depression in the HIV population

A complex interaction of biological, social and psychological vulnerabilities cause depression (28). Currently, scholars argue that the biopsychosocial model may not sufficiently explain causation of mental disorders, including depression, as spiritual beliefs, rituals and community habits have been found to be important aspects in defining and understanding depression (29).

Studies demonstrate that depression consistently shows an association with socio-demographic adversities (30). Causal pathways of socio-demographic adversities and depression are not well understood, and the association seems mixed. Socio-demographic adversities can be outcomes of depression but can also cause depression. Lund and colleagues describe social causation and social drift theories, demonstrating that poverty is an important social adversity that can be a causative factor (31). In addition, a range of social determinants, particularly demographic, socio-economic and social changes associated with depression (32).

HIV/AIDS is a chronic, life threatening, and stigmatising disease, affecting the general wellbeing of PLWHA to a high extent (33). Due to HIV/AIDS, PLWHA are vulnerable to socio-economic adversities such as job loss, unemployment and poverty (34).

The findings of previous studies in the HIV population indicated that psychosocial problems have shown strong correlations with depression. For example, life changes (such as poverty, job loss, unstable employment, sickness) (32) and social problems (such as divorce and separation, low social support and social isolation due to stigma) due to HIV/AIDS all increase the risk for depression (35). Commonly reported psychosocial problems such as stigma, conflict and interpersonal violence could lead to low self-esteem, helplessness or the onset of full-blown depression (36-38). The most reported risk factors for depression in PLWHA can be categorised as socio-demographic (39), psychosocial (40) and clinical (41). Low income, being jobless, marital separation/divorce, low perceived social support, being female, large family size and stigma are the most common socio-economic and socio-demographic factors associated with depression (18, 41, 42). Psychological factors such as maladaptive coping strategies, including substance use (43, 44), self-stigma (37, 38), and negative self-image (36, 38) are commonly associated with depressive symptoms.

1.3. Depression and Quality of Life

Quality of Life (QoL) refers to the general wellbeing of an individual that involves several domains of functioning, namely physical, psychological, independence, social, environmental and spiritual, and can be affected by a variety of life circumstances (45, 46). Depression affects the QoL of PLWHA in various ways (47-50). Mood disturbance commonly associated with poor QoL (51, 52) and MDD has been reported to correlate with lower scores of psychological, social and environmental domains of QoL (53). Depression is believed to reduce immune functioning and exacerbate immune suppression (22). Poor immune functioning leads to the advanced stage of AIDS which can further lead to deterioration in physical, psychological and social health (54).

Depression may also affect QoL indirectly through affecting adherence to HIV treatments leading to poor adherence and immunological outcomes, high viral load and an increased risk of mortality (55). PLWHA who have comorbid depression are more likely to have low treatment adherence than those without depression (56). This is supported by a systematic review of randomised controlled trials that shows that depression has a negative association with adherence to ART (57). This can be partially explained by the demotivation to adhere to HIV treatments due to affective symptoms of depression, negative thinking (for example, hopelessness about the future) and suicidality. Moreover, neurocognitive symptoms of depression, such as forgetfulness, can also explain the temporal relationships of depression with poor adherence to ART. Poor ART adherence, advanced clinical stage of AIDS, late ART initiation, poor immunological status (low CD4 count) and comorbid physical illness are all reported to contribute to poor QoL (41, 58). Figure 1 illustrates the association of HIV/AIDS, depression and health-related outcomes of PLWHA.

Given the above body of evidence on the burden of depression and its effects mainly on adherence to HIV treatment and overall QoL of PLWHA, the development of evidence-based and acceptable interventions should be a priority to break the cycle between depression and poor QoL. In LMICs where less than 10% of the population has access to basic mental health care (59), the need to get affordable, accessible and effective interventions for depression remains high, especially for vulnerable groups of people, including PLWHA.

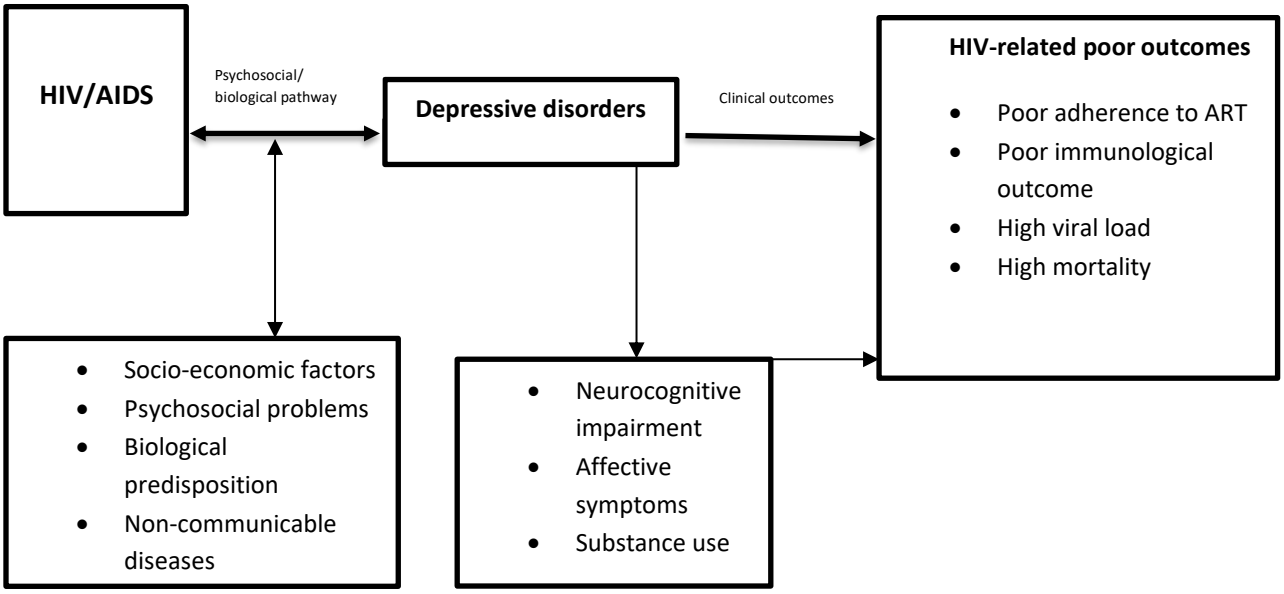

Figure 1. Conceptual framework linking HIV/AIDS, depressive disorders and health-related outcomes.

Adapted from *Chibanda et al. 2014 (60).*

1.4. Treatment gap and the role of psychological treatments

This section reviews literature in relation to the mental health treatment gap and its contributing factors in LMICs, particularly in Ethiopia. It describes the mental health treatment gap particularly among PLWHA in LMICs, with particular emphasis on Ethiopia. It also summarises the role of evidence-based psychological treatments to reduce the existing mental health treatment gap, particularly for PLWHA, using a task shifting approach. Task shifting, defined as "delegating tasks to existing or new cadres with either less training or narrowly tailored training, is a potential strategy to address these challenges" (61).

1.4.1. Treatment gap

Although effective mental health interventions are available, only a few people with depression are receiving treatment in LMICs (62). Whilst 80% of people with mental disorders reside in LMICs, the provision of mental health care is inadequate (63). Among people with depressive disorders, only 1 in 5 in high-income countries and 1 in 27 in LMICs are receiving even minimal treatment (64). More than 90% of people who need any mental health interventions are not receiving care and treatment in LMICs (59, 65, 66). The challenges contributing to this huge mental health treatment gap are complex. Most low-income countries have no stand-alone mental health policy or strategy and as a result the mental health services suffer from inadequate funding and limited access to evidence-based interventions (63-65, 67). In addition, the lack of mental health facilities and infrastructure (67) and the scarcity and maldistribution of trained human resources are major barriers to closing the treatment gap (65). Mental Health treatment gap is not limited to the lack of available services but also affected by low demand of mental health care services at community level. These demand related factors include mental health stigma and cultural norms of visiting traditional healers or faith healers which can discourage modern health service utilisation (68-70). Lack of information about availability of mental health services, Lack of awareness about mental health problems are also major contributors to low demand of mental health services (68, 70). To increase mental health demand, it is important to increase awareness and access to information through using media and community leaders.

Mental health treatment gap "refers to the difference that exists between the number of people who need care and those who receive care" (71). Mental health care services in LMICs are commonly challenged by unmet needs that is due to the large gap between the need for and provision of mental health services (72). The treatment gap has become an important concept widely promoted by the WHO through the development of the mhGAP approach, which has been

demonstrated to have many benefits in building mental health services. However, its limitations should be addressed critically (71). The concept of mental health treatment gap is partially obscures due to the complex assemblage of therapeutic approaches which does not take variety of treatment choices (73). Because the concept of mental health treatment gap is conceptualised at “community” level and that does not allow to provide person centred care at individual level although it increases economic efficiency by reducing health care costs for LMICs (71).

Ethiopia, a country with more than 100 million people, has no stand-alone mental health policy and legislation (74). According to the 2017 WHO Mental Health ATLAS report, the total number of mental health professionals is 1,739, with a proportion of 1.74 per 100,000 population. The ratio of mental health nurses, psychiatrists and psychologists is 1.00, 0.08 and 0.04 per 100,000 population respectively. The treatment gap remains high and the existing health care system seems incapable of addressing mental disorders, including depression (75). In Ethiopia, the mental health report of 2006 indicated that 1.7% of the national health budget was allocated to mental health care (76), even though mental disorders had become the leading contributor to the disease burden caused by non-communicable diseases in Ethiopia (77).

Given the large body of evidence on the existing mental health treatment gap described above, there is a clear need for the early detection and treatment of depression and other mental disorders along with existing HIV care (78). The health care of PLWHA has focused on biomedical treatments, leaving mental health problems relatively neglected (79). Depression, the most common mental health condition in PLWHA is responsive to a variety of treatments (80). However, the lack of evidence-based interventions, low mental health funding and lack of trained human resources has created huge a mental health treatment gap in Ethiopia. It is important to develop and revise mental health policies and utilise human resources more efficiently, such as using a task shifting approach by capacitating non-specialists to deliver psychological treatments (65).

1.4.2. The role of psychological treatments

Psychological treatments play an important role in preventing and treating mental health conditions (81). Several psychological treatments are proposed as being effective for treatment of depression (82) and also in preventing the onset of depressive disorders (83). Evidence-based and cost-effective psychological treatments that are used to facilitate recovery from depressive disorders have been emerging around the world (84). A recent systematic review and meta-analysis of trials reported that psychological treatments are as effective as antidepressants in

reducing depression relapse (85). Another systematic review found that psychotherapies are equivalent in effectiveness to pharmacotherapies for the treatment of adult depression (86). Studies from high-income countries have indicated that psychological treatments that included cognitive behavioural therapy (CBT) are more effective than other psychological treatments (82). A systematic review of psychotherapies among adolescents with depression globally found interpersonal therapy (IPT) to be as effective as CBT, with more advantages in long-term effectiveness and higher attendance rates (87). The most recent systematic review on LMICs, presented in Chapter 2 of this thesis, has shown higher effect sizes using psychological treatments such as IPT (standard mean difference (smd) = -1.72; 95% confidence interval (CI): -3.21,-0.23) instead of CBT (smd = -0.03; 95%CI: -0.27,0.21) (88). More research in LMICs has found high effectiveness in treating depression among different groups of people using IPT (84, 89, 90). The success of IPT in LMICs poses the question of whether interpersonal theories are more important to explain depression than cognitive behavioural models in non-Western cultures (91) which is an important consideration for psychological therapies in countries like Ethiopia. IPT reduces depressive symptoms through enhancing social support, solving social disputes and conflict, and managing life changes (88).

A systematic review and meta-analysis of trials in LMICs, presented in Chapter 2 of this thesis, found that both group- and individual-based psychological treatments are effective and there was no difference in effect size between the two approaches (88). Group-based psychological treatments have shown high acceptability in African cultures as evidenced by high treatment adherence and effectiveness (90). Verdeli and colleagues argue that group-based psychological treatments increase intervention coverage at a lower cost as compared to individual-based interventions (92). This is further supported by more recent reports by Rose-Clarke and colleagues (93) and Collins and colleagues (14) that group-based psychological treatments could be more cost-effective than individual-based interventions. Group-based interventions facilitate social support, enable the learning of problem-solving skills, promote group motivation and enable learning of new coping strategies (94). Symptom-specific evidence-informed counselling, psychoeducation and group-based IPT may be effective for the treatment of depression (80). Group IPT can be delivered by non-professionals successfully and can be a useful intervention for multiple cultural settings following cultural adaptation (14). However, there may also circumstances in which group-based interventions may not work, for example when groups are heterogeneous in terms of age, gender, educational status and socioeconomic class. Group-based interventions may not be successful when confidentiality is a big concern (95, 96).

Psychological treatments that can be administered by non-specialists after a short period of training could have major implications for addressing the shortage of trained human resources in LMICs. Study findings have shown benefits for the treatment of depression using non-specialist administered psychological treatments (97). Non-specialist health workers are primary level health care providers who have received more general mental health training rather than specialist level training such as psychologists and psychiatrists (65). The use of non-specialist counsellors can be an economically feasible method of increasing the number of trained human resources for LMICs (98). In addition, non-specialist counsellors can usually speak the same language and share the same culture as their clients, allowing them to understand what is appropriate for the culture in a specific community (99, 100). Culturally adapted, non-specialist administered, group-based psychological treatments need to be accessible to PLWHA (81). All psychological treatments may not be uniformly effective when implemented in various settings and in different populations. Therefore, systematic cultural adaptations may be a requirement to optimise the acceptability and effectiveness of psychological treatments in the HIV population.

1.5. Approaches to adapting psychological treatments

Psychological treatments may not be consistently effective in every culture and setting due to several interacting barriers during their implementation. This becomes a challenge for worldwide scalability (81). The barriers that affect the implementation of these treatments include low acceptability and feasibility, the lack of proper adaptation of interventions when using for different populations, and the low competency of the administering agents (101, 102). Mental health stigma (enacted and self-stigma) and low mental health literacy can also hinder the delivery of quality care (70).

Most psychological treatments have been developed in “Western countries” and, although several studies have examined their effectiveness in LMICs (103), may not be equally effective in LMICs due to the lack of systematic cultural adaptation to “non-Western” settings (104). The adaptation of psychological treatments has become an important method to optimise the acceptability and effectiveness of an intervention (93, 105). This is supported by two meta-analyses that found that culturally adapted psychological treatments are more effective than those non-adapted interventions (104, 106), although a third meta-analysis indicated no evidence for association between adapted interventions and effect size (103). The WHO recommends psychological treatments such as IPT and CBT as the first line treatment choice for depression after proper cultural adaptation and contextualisation (107). More recently, psychological treatments have

been adapted and tested in some LMICs and appeared to be effective for depression (88, 108). The adaptation of psychological treatment requires an understanding of the cultural explanations of illness and treatment preferences of the specific population (109).

Common areas of adaptation include systematic language adaptation, such as the literal translation and inclusion of metaphors, and the use of idioms and local stories (104), and content adaptation, such as the modification of core components of an intervention (110). The lack of adaptation guidelines has led researchers to adopt different approaches ranging from haphazard and non-empirical methods to more systematic and participatory approaches guided by conceptual frameworks through engaging the local community and stakeholders (93). While conducting cultural adaptation, studies suggest including three important components: i) cultural concepts of illness; ii) core treatment principles of therapies; and iii) strategies of treatment delivery (105).

Several studies have used the ecological validity and culture sensitivity model (111) to conduct cultural adaptation. This model is a broad framework that addresses several components of cultural adaptation, such as a local conceptual understanding of an illness, the use of culturally appropriate language, the selection of preferred delivering agents, and strategies for successful delivery of the selected intervention (111). Within the ecological validity and culture sensitivity model, nesting sub-frameworks may be important to explore each component in more detail. For example, including explanatory models of illness (112) allows us to explore the conceptual understanding and treatment preferences of a specific community. Similarly, the use of stepwise and participatory approaches, such as Participatory and Iterative Process Framework for Language Adaptation (PIPFLA), enables us to conduct appropriate language adaptation. The WHO has drafted a protocol for the adaptation of psychological treatments for common mental problems, including for depression, into the local context (113). This includes a stepwise language and content adaptation of evidence-based psychological treatments with special emphasis on the use of non-specialist counsellors in low resourced settings. Therefore, the findings of this thesis can be used to inform possible further changes to the WHO adaptation protocol.

1.6. Health care system and mental health services in Ethiopia

The Ethiopian health system comprises a three-tier system of care that incorporates primary, secondary and tertiary care systems (77). The primary care level is established at district level and comprises health posts, health centres and primary hospitals. The primary level of care uses a task shifting approach to provide basic health services at the community level. Most of the

functions conducted by Health Extension Workers (HEWs) at community level are health education, health promotion and provision of other basic primary care services. Most importantly, people with more serious health issues, including severe mental conditions, are usually referred by HEWs to secondary or tertiary care services, although the national Mental Health Strategy indicates that referral of people with severe mental disorders should be to primary care (health centres). More than 38,000 HEWs have been deployed across the districts since 2003 and this has been reported to be an effective approach in accessing basic health care for the community (114). This shows the potentially available human resources for improving mental health care coverage through a task shifting approach. These human resources can be trained to provide psychological treatments in ART clinics found in health centres, and district and referral hospitals. In ART service centres, there are different cadres of care providers, these includes physicians, health officers, nurses, pharmacists, laboratory technologist. There are also non-professional supportive staff members such as case managers (HIV counsellors), adherence supporters (adherence counsellors) and volunteers. All these human resources, particularly non-professionals can provide psychological treatments for PLWHA if they are supported by trainings.

The Federal Ministry of Health (FMOH) started to move towards the development of accessible, affordable and acceptable mental health care by introducing a strategic mental health plan for the period between 2012/13 and 2015/16 (115). The strategic plan was in place for a brief period and there are plans for a new strategic mental health plan to be developed in the future. The strategic plan strongly advocates for the efficient utilisation of existing resources when integrating mental health services into the primary level of care. The WHO Mental Health Gap Action Programme (mhGAP) conducted a pilot study by integrating mental health care services into the existing health care system using a task shifting approach in collaboration with the Ethiopian Ministry of Health (116). The pilot programme, that aimed to efficiently utilise the existing resources, has successfully addressed the basic mental health needs of people residing in selected areas in the Amhara, Oromia, Tigray and South Ethiopia regions. However, the detection rate particularly for depression was very low, with only 89 individuals identified with depression in 19 clinics in a six-month period. This highlights how detection of depression is challenging for primary care clinicians. Other studies also found supporting evidence that 98% of cases with depression remained undetected in primary health care settings (75). The WHO mhGAP has continued providing mental health training for non-professionals, however the scale-up has been very slow in Ethiopia. The approach has been reported to be successful and could greatly contribute to reducing the treatment gap and mental health morbidity.

1.7. HIV/AIDS and mental health care services in Ethiopia

In Ethiopia, the estimated prevalence of HIV/AIDS among adults (15-49) was 1.1% and it was estimated to be 0.9% among all age groups. This means that close to a million people have HIV/AIDS, according to the 2016 Demographic and Health Survey of Ethiopia (117). The trend of HIV prevalence has been significantly higher in urban (2.9%) than in rural areas (0.4%), and the Northwest, Northeast and Southern parts of the country were demarcated as high risk areas for HIV infection (118). In 2016, a total of 30,000 people were estimated to be infected with HIV and 20,000 deaths had occurred due to HIV/AIDS (117). HIV services are provided at all levels of care services, these are at primary (at health posts and health centres), secondary (primary and district hospitals) and tertiary (specialised hospitals) level.

The national mental health strategy of Ethiopia has developed an integrated care approach to address mental disorders with a particular emphasis on addressing mental, neurological and substance use disorders such as depression, psychosis and epilepsy (119). The Ethiopian health care policy for HIV focused on accessing ART treatments, and the integration of mental health services with HIV care received minimal attention (12). In line with the general mental health services described above, the integration of mental health services with the existing HIV care services has been piloted in some parts of the country and the integration model was found to be promising (80).

Even though the Ethiopian government developed a strategy to integrate mental health services with HIV/AIDS care, there has been no specific trial conducted to adapt and examine the effectiveness of group IPT for PLWHA. Group-based IPT can be relevant to resource-limited settings to address difficult-to-reach communities as it can be delivered by non-specialists who received basic training. Examining the acceptability and feasibility of group IPT for PLWHA is an important step before conducting a randomised controlled trial to test its effectiveness. This thesis addresses this initial step as described in the next section.

1.8. Rationale for the thesis

Early treatment of depression can facilitate positive engagement with HIV care and treatment and can improve clinical outcomes of HIV. Although several studies have contributed a lot of evidence in showing the prevalence of probable depression using screening tools in PLWHA in Ethiopia, little has been done towards: i) assessing the burden, risk factors and outcomes of MDD; ii) developing or adapting evidence-based psychological interventions for depression for PLWHA;

iii) implementing effective interventions for treatment of depression to improve the overall QoL of PLWHA. More research is needed on adapting and developing evidence-based interventions that can work in harmony with the existing health care system. Prior to the implementation of evidence-based interventions, the assessment of risk factors and outcomes of depression helps in identifying areas for intervention. It is also important to evaluate the acceptability and feasibility of evidence-based interventions and to examine the effectiveness of the interventions. This thesis presents the findings from the adaptation and pilot evaluation of a group IPT intervention for depression for PLWHA in Ethiopia. Unlike previous studies in the HIV population in Ethiopia, this thesis assessed the prevalence of MDD using a diagnostic instrument and examined its association with adherence to ART and QoL. The thesis also identified important areas for intervention for PLWHA. The areas for intervention were identified by factors associated with depression and exploring perceived causes of depression among PLWHA. Therefore, the findings of this thesis can contribute important insights to mental health research. The findings of this thesis further contribute to showing the process used in adapting and examining the acceptability and feasibility of psychological interventions for PLWHA and piloting an intervention that can be used in future trials. Moreover, the results of this thesis can be utilised by mental health researchers interested in adapting and implementing interventions, particularly in the HIV population.

1.9. Aims and objectives

The overall aim of this thesis was to generate new knowledge on the needs for depression care and the feasibility and acceptability of a psychological treatment for depression among PLWHA in Ethiopia. This will be addressed by the following four objectives.

1. To systematically review the effectiveness of psychological treatments for depressive symptoms for PLWHA in LMICs: a systematic review and meta-analysis;

2. To determine the prevalence of MDD and its association with adherence to ART and QoL: A cross-sectional survey of PLWHA in Northwest Ethiopia;

3. To adapt the WHO group IPT for the treatment of depressive symptoms for PLWHA in Ethiopia specifically for delivery by trained non-specialists;

4. To pilot the adapted group IPT intervention, and to assess its acceptability and feasibility for treatment of depressive symptoms for PLWHA in Ethiopia.

1.10. Overview of chapters

Each objective of this thesis is presented in a separate chapter, from Chapters 2 to 5, with each chapter providing findings that inform a specific objective. Chapter 2 presents the systematic review and meta-analysis of randomised controlled trials that investigated the effectiveness of psychological treatments for depression for PLWHA in LMICs and provides evidence that group IPT is a good candidate for treating depression among PLWHA.

Chapter 3 reports the findings of the baseline study that determined the association of MDD with adherence to ART and QoL of PLWHA. The evidence presented in this chapter helps to identify areas for intervention that supported the findings of the systematic review. It shows that there was a positive relationship between MDD and functional disability, optimal adherence to ART and low QoL.

Chapter 4 presents the findings explored in adapting the group IPT intervention and the frameworks used to explore areas for the possible integration of group IPT in HIV care. This chapter sets out the steps and activities that were conducted in the adaptation of the intervention and summarises the findings. The WHO group IPT with its forms and structures was perceived to be appropriate for PLWHA if it is administered by peer-counsellors.

Chapter 5 presents the findings of the pilot study of the adapted group IPT intervention and discusses important areas that should be addressed in future. The process of the intervention and its outcomes were acceptable, and the intervention was perceived as feasible. This chapter also presents both quantitative and qualitative findings of the intervention and the application of group IPT for PLWHA.

Chapter 6 presents a synthesis of the findings in an overall discussion and conclusion of the thesis, with limitations of the study and recommendations for mental health researchers, stakeholders in HIV care and policy makers.

1.11. Study setting and preparations for the study

This study was conducted in the ART clinic in Felege Hiwot Referral Hospital (FHRH), which is the largest comprehensive referral hospital in Northwest part of Ethiopia. FHRH is located in Bahir Dar and serves a population of 7 million people in the catchment area. Bahir Dar is the capital city of the Amhara regional state where the regional government is located. Bahir Dar is the largest urban settlement in the Northwest part of Ethiopia, which is home to 750,000 people. Of these,

93.2% are from the Amhara ethnic group and 95.5% speak Amharic as their first language. More than 79.7% of the population practice Ethiopian Orthodox Christianity and 18.5% are Muslims. See the location of the study setting in Figure 2.

A few months prior to starting the field work, I had visited the research setting and met local organisations working with PLWHA and other stakeholders, including the regional health bureau, head of the ART clinic, ART nurses, HIV counsellors and service users, separately. The purpose of these meetings was to identify the available resources to and short- and long-term needs of the stakeholders, and to identify the motivating factors for the stakeholders. These meetings were the first milestone in establishing a foundation for alliance and in getting buy-in to the research. Later, my supervisor (MS) and I visited the facility and the HIV care system of the study setting. We met some of the staff members at the ART clinic and received feedback on how to conduct the research and to further strengthen collaboration. I arranged a seminar to officially launch the research in collaboration with the College of Health Sciences of Bahir Dar University and made a presentation on the aims of the research to stakeholders and invited guests. I received constructive feedback from participants on how to put the protocol into practice. I presented the research purpose to ART nurses, case managers, adherence supporters and mental health professionals, and explained their contribution to the research and reaffirmed the goals of the research. The implementation of the research was conducted in consultation with the stakeholders. Training and data collection were arranged and provided at the convenient times as suggested by the stakeholders and in communication with the ART clinic head. The research team remained consistent throughout and until the completion of the research work without any drop-out of research staff.

I, the principal investigator of this thesis (a mental health professional based in Northwest Ethiopia), coordinated all tasks of the field work, was involved in organising the group IPT training, provided the training with the three other trainers, oversaw the data collection and arranged facilities for the implementation of the group IPT. I was also responsible for communicating with officials at the College of Medicine and Health Sciences of Bahir Dar University to obtain a training hall for workshops and training. I reviewed the quality of the data on a regular basis and checked the completeness of the collected data. However, I was not involved in any of the survey data collection, focus group discussions, group IPT sessions or post-intervention interviews. All the activities of the research were conducted based on my guidance.

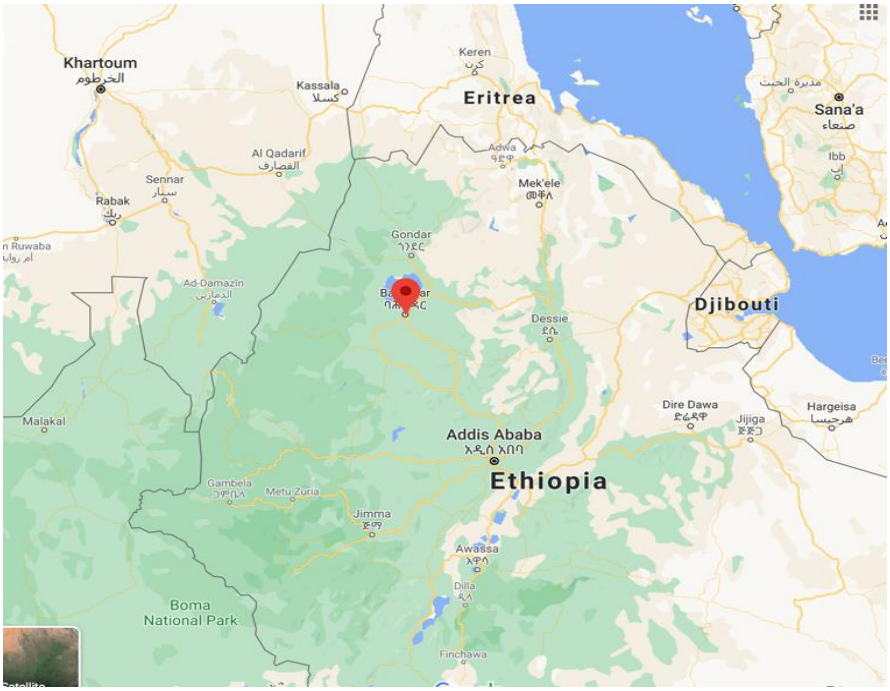

Figure 2. The red spot on the map indicates the location of study area. The map was taken from google earth.

Chapter 2. Effectiveness of psychological treatments for depressive symptoms among people living with HIV/AIDS in low- and middle-income countries: a systematic review and meta-analysis

Biksegn Asrat[1], Marguerite Schneider[1], Fentie Ambaw[2,4], Crick Lund [1,3]

[1]Alan J Flisher Centre for Public Mental Health, Department of Psychiatry and Mental Health, University of Cape Town

[2]School of Public Health, College of Health Sciences, Bahir Dar University

[3]Centre for Global Mental Health, King's Global Health Institute, Department of Health Services and Population Research, Institute of Psychiatry, Psychology and Neuroscience, King's College London

[4]Department of Psychiatry, College of Health Sciences, Addis Ababa University

My contribution

I conceptualised the study and led the data extraction, analysis and interpretation of results. More specifically, I developed the systematic searching strategy and lead the search for articles from data bases. I contributed in quality appraisal of articles to be included in the systematic review and meta-analysis. I drafted the initial and revised subsequent versions of the manuscript. The three co-authors are all involved as supervisors and provided guidance at all stages and reviewed all drafts of the manuscript.

2.1. Abstract

Background: Psychological treatments play a significant role in managing depressive symptoms. However, little is known about the most effective psychological treatments for depressive symptoms for PLWHA in LMICs.

Aims: To identify effective psychological treatments to manage depressive symptoms for adult PLWHA in LMICs and to estimate pooled effect sizes using a meta-analysis.

Method: Four databases were searched using key words and MeSH terms – PubMed, Scopus, Cochrane library and PsychINFO. The inclusion criteria were randomised controlled trials that examine psychological treatments that target depressive symptom for adult PLWHA in LMICs. The Cochrane risk of bias tool was used to assess the risk of bias. A meta-analysis was done using RevMan-5.

Result: Nineteen studies were included in the systematic review and 14 of them were selected for meta-analysis. Eight (42%) of the trials used CBT. Pooled effect size of trials that used continuous outcomes was -0.61 (n=12; 95%CI: -1.24,0.02; I^2=95%) at post-treatment assessment. The pooled effect size changed to -1.41 (n=8; 95%CI: -2.54, -0.28; I^2=98%) at six months post treatment.

Limitations: Studies varied in quality from low to high risk of bias and there was high heterogeneity across studies.

Conclusion: Trials used group support psychotherapy (GSP), IPT, problem-solving therapy (PST), and peer-support counselling were effective in reducing depressive symptoms. However, better powered studies with more consistent methodologies are needed to investigate whether specific therapies delivered by lay counsellors are effective for PLWHA in LMICs.

Key words: Depressive symptom, Psychological treatment, HIV/AIDS, LMICs

2.2. Introduction

PLWHA commonly experience depressive symptoms due to their vulnerability to stressful life circumstances, including living with a life-threatening illness (14). Depressive symptoms are associated with disease progression and poor health-related outcomes in PLWHA (120).

Psychological treatments play a significant role in managing depressive symptoms, including among PLWHA (121). These treatments have been preferred over pharmacotherapy (122) due to their flexibility, limited side effects and relatively low cost (123). However, variation in implementation due to cultural differences (for example idioms of distress used in psychological treatments may vary across cultures) and the lack of consistent measures to compare their effectiveness makes it difficult to choose one over the other (82, 124).

Although studies from high-, middle- and low-income countries indicate that a variety of psychological treatments are successful in reducing depressive symptoms for PLWHA, there is variable and inconclusive evidence on what is the most effective psychological treatment (33, 125-129).

To illustrate, a systematic review and meta-analysis of 13 group-based CBT treatment for depressive symptoms of PLWHA found a small pooled effect size for group CBT in the reduction of depressive symptoms smd = -0.26; 95%CI: -0.42,-0.10) (33). In contrast, a systematic review of four group CBT trials indicated a larger pooled effect size (smd = 2.07; p=0.01) on the reduction of depressive symptoms in PLWHA (130). The effectiveness of psychological treatments may be influenced by several factors including cultural factors, level of competency of therapists and format of delivery.

In relation to studies in LMICs a review of randomised controlled trials of psychological treatments of common mental disorders for PLWHA was conducted by Chibanda and colleagues (131). The studies included in this review were few (only five trials included), but three of them had a high risk of bias and there was high heterogeneity in the nature and duration of treatment. This review did not indicate what type of psychological treatment and what format of delivery (group or individual) are the most effective and acceptable for treating depressive symptoms for PLWHA. A more recent systematic review was conducted of psychological treatments for depressive symptoms for PLWHA in Africa (132). This review included 18 studies with diverse methodologies (including cohort, quasi-experimental and randomised controlled designs). Of the included studies, seven used anti-depressant medications, seven used different psychological treatments

and the remaining used physical exercise and other unspecified psychosocial interventions. This review showed that the use of psychological treatments for depressive symptoms was acceptable and feasible in PLWHA in sub-Sahara Africa (SSA). This review did not compare effectiveness of each treatment, instead authors commented on the need for large studies to show efficacy (132). An overall review of mental health interventions identified a paucity of empirical data investigating effectiveness of treatments for mental disorders for PLWHA in LMICs (133). The data were widely diverse in terms of treatment approach, methodologies used and sample size. Therefore, it was not possible to identify the most effective treatment to improve mental health of PLWHA. The three systematic reviews conducted in this area have made important contributions to our understanding of psychological treatments in the HIV population. However, none of them have conducted a meta-analysis to compare the effectiveness of psychological treatment types in reducing depressive symptoms. Furthermore, as stated by the authors in the article using the Cochrane collaboration risk of bias tool, most studies included in their reviews were of poor quality making it difficult to assess the most effective psychological treatment in resource limited settings.

In general, studies from different setting have shown that both CBT and IPT seem to be effective in reducing depressive symptoms among PLWHA. However, there remains limited information available on the best psychological treatments for depressive symptoms for PLWHA in LMICs. Hence, the overall aim of this review and meta-analysis was to identify the most effective psychological treatment and to quantitatively pool effect sizes. The current systematic review and meta-analysis aimed to update the previous reviews (131-133). Newly published trials are identified, and their finding analysed together with the findings of the previous studies (studies published before 2015).

2.3. Method

We searched for studies evaluating psychological treatments targeting depressive symptoms among PLWHA in LMICs. The protocol was registered in PROSPERO (CRD42018093949). The PRISMA checklist for reporting of systematic reviews and meta-analysis was used (134).

2.3.1. Inclusion Criteria

The general criteria for including articles were: (1) the study must be conducted among adult PLWHA with age ≥18 years; (2) the study should include depressive symptoms as a primary or secondary outcome; (3) the study must be an RCT; (4) the intervention used in the study must be a psychological treatment in any format in any setting; and (5) the study must be conducted in LMICs.

2.3.2. Exclusion criteria

The exclusion criteria were: (1) studies comparing effectiveness of psychological treatments among people with and without HIV/AIDS; (2) studies using psychological treatments and pharmacotherapy concurrently; and (3) including depressive disorders with psychotic features; (4) papers published other than in English.

2.3.3. Literature search strategies

A total of four databases (PubMed, Scopus, Cochrane library and PsychINFO) were searched from mid-August to the beginning of September 2018. We did not set any date restrictions on our search. PubMed and Scopus were searched on 16th and 28th August 2018 respectively. Both Cochrane library and PsychINFO were searched on 5th September 2018 using the selected search terms. Studies published in PubMed and Scopus before 16th and 28th August 2018 respectively were retrieved. Furthermore, studies published in the Cochrane library and PsychINFO before 5th September 2018 were retrieved. The key terms used for searching articles were (1) psychological interventions (2) depression and (3) HIV/AIDS. The "all field" and "MeSH term" searches were used for all key terms in PubMed. Psychological interventions were searched using search terms such as – "*psychological intervention" OR* "*psychological treatment" OR "psychosocial intervention" OR "psychoeducation" OR "counselling" OR "psychotherapy" OR "group psychotherapy" OR "cognitive therapy" OR "cognitive behavioural therapy" OR "interpersonal therapy" OR "problem-solving therapy" OR "psychodynamic therapy" OR "psychodrama"* along with the MeSH terms. The key term "depression" was searched using the term "*depression*" and its synonyms such as – "*depressive symptoms" OR "depressive disorders" OR "depressed mood" OR "major depressive disorder" OR "affective disorder"*. Many MeSH terms for depression were included to broaden the search result, such as "depression", "depressive disorder", "depression, postpartum", "depressive disorder, major", "dysthymic disorder". The key term "HIV/AIDS" was searched using "*HIV" OR "AIDS" OR "HIV/AIDS" OR "human immunodeficiency virus" OR "acquired immunodeficiency syndrome"* using the 'all' field and MeSH terms. The settings were searched from PubMed and PsychINFO using the detailed list of LMICs from the World Bank report 2018 at this link http://data.worldbank.org/about/country-and-lending-groups. In the Scopus search, we managed to exclude the list of high-income countries to narrow the setting specific to LMICs. However, in the Cochrane library search all trial studies around the world were included. We linked the key terms using the Boolean operator "AND" such as: *(("psychological intervention" OR "psychosocial intervention" OR "psychoeducation" OR "psychotherapy") AND ("depression" OR "depressive disorder" OR "depressive symptoms" OR*

"Affective disorders") AND ("HIV" OR "HIV/AIDS" OR "human immunodeficiency virus" OR "AIDS" OR "acquired immunodeficiency syndrome") AND (world bank list of countries in LMICs)). The full search strategy can be accessed from the PROSPERO at this link https://www.crd.york.ac.uk/PROSPERO/#recordDetails. In addition, the references of published papers were searched manually.

2.3.4. Study selection

Studies identified were screened by topic and exported to the EndNote X9 software. Duplicate studies were removed from the EndNote X9 and the remaining studies underwent abstract screening. The studies which fulfilled at least four of the five inclusion criteria were selected from the abstract reading. The full articles of the selected studies were searched by BA. BA and MS assessed the full articles using the inclusion criteria. When there was a discrepancy between BA and MS a third reviewer (CL) was consulted and a decision reached by consensus.

2.3.4. Data extraction and management

The data extraction was conducted by the first author, in consultation with other authors. Data were extracted from the studies which fulfilled all the inclusion criteria using the Cochrane collaboration data collection form for RCTs. The extracted data included publication year, country, setting, sample size, type and format of intervention, result, and key conclusions. All relevant data in each study were extracted from the data extraction form for the systematic review and meta-analysis. The characteristics and results of each study were summarised and presented in tables and figures.

2.3.5. Assessment of risk of bias in individual studies

Authors evaluated each study independently using the Cochrane collaboration risk of bias tool (135). The tool has seven evaluation criteria: random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases. For each of these criteria a study was rated with a low risk of bias or high risk of bias. For example, 'Random sequence generation' was judged as being low risk of bias if the study used a clearly stated random sequence generation method such as the use of random number table, using a computer number generation, coin tossing, throwing dice or use of envelops/cards. 'Random sequence generation' was judged as 'high risk' of bias if the study used a non-random method for sequence generation process, such as using date of birth, using day/date of admission, or medical record number. A study was rated 'good quality' when all the seven criteria were judged as *low risk of bias*, 'fair quality' when one of the seven criteria were

judged as *high risk of bias*, or 'poor quality' when two or more criteria were rated as *high risk of bias*.

Two of the authors (BA and MS) evaluated each paper using the Cochrane risk of bias tool independently. Then BA, MS and CL met together to assess whether interrater disagreement occurred. The results of the evaluation were presented, and a final decision made by the reviewers (BA, MS and CL) on which studies to include for meta-analysis. Studies were selected for meta-analysis if they had complete data for the analysis and if they have low risk of bias on at least two criteria of the Cochrane risk of bias tool.

2.3.6. Analysis of treatment effect

The aim of this review was to identify effective psychological treatments and to examine the extent of their effectiveness in reducing depressive symptoms for PLWHA. We conducted a meta-analysis to quantify pooled effect sizes and heterogeneity of studies. Data collected from each study were entered into the Cochrane collaboration Review manager (RevMan-5) for meta-analysis. Effect size (standardised mean difference) was calculated by taking score differences between the intervention and the control groups after treatment. The after-treatment score difference was taken with the assumption that there was no significant difference in depressive symptoms between the intervention and control arms at baseline since the included studies were RCTs. Individual and cumulative effect size (standard mean difference (smd)), heterogeneity status (I^2) (136, 137), and forest plots were generated using random effect analysis. Random effect analysis was used because we expected considerable heterogeneity across studies (136). The analysis of the effect size of continuous and dichotomous outcomes of depressive symptoms was done separately. Sub-group analysis of the effect size was calculated by (1) types of psychological treatment (CBT, IPT, peer-support psychoeducation/counselling and other interventions); (2) format of delivery of the treatment (group-based and individual-based); (3) training level of therapists (psychologist-delivered and non-psychologist-delivered); and (4) by follow-up evaluation status (post-intervention/immediately after treatment and after 6 months follow-up). Publication bias was assessed using a funnel plot. The funnel plot was interpreted through visual inspection of the distribution of plots (studies) around the funnel. The Egger's test of intercept was conducted to identify sources of asymmetry in the funnel plot.

2.4. Results

2.4.1. Characteristics of the included studies

Of 1696 screened articles, 179 duplicates were removed. After removal of duplicates, 1107 articles were excluded because they did not fulfil at least one of the inclusion criteria – i.e. studies from high-income countries, studies among non-HIV population, and other mental health outcomes. Full text review of 410 articles was conducted to check whether they fulfilled at least 4 of the 5 inclusion criteria. Afterwards, 64 studies were screened further using all the inclusion criteria. This resulted in 45 articles being excluded from the qualitative review due to the following reasons: 12 studies were not intervention studies and included cohort and case-control studies, 10 studies were done in mixed populations which included HIV-positive and HIV-negative participants, six studies were done among children or adolescents, four were RCT protocols, three were quasi-experimental, three were qualitative studies, three were non-psychological interventions (an aerobic exercise, laughter therapy, and palliative care), two were expert opinions, one was not in LMICs and one was in a Chinese language. See Figure 3.

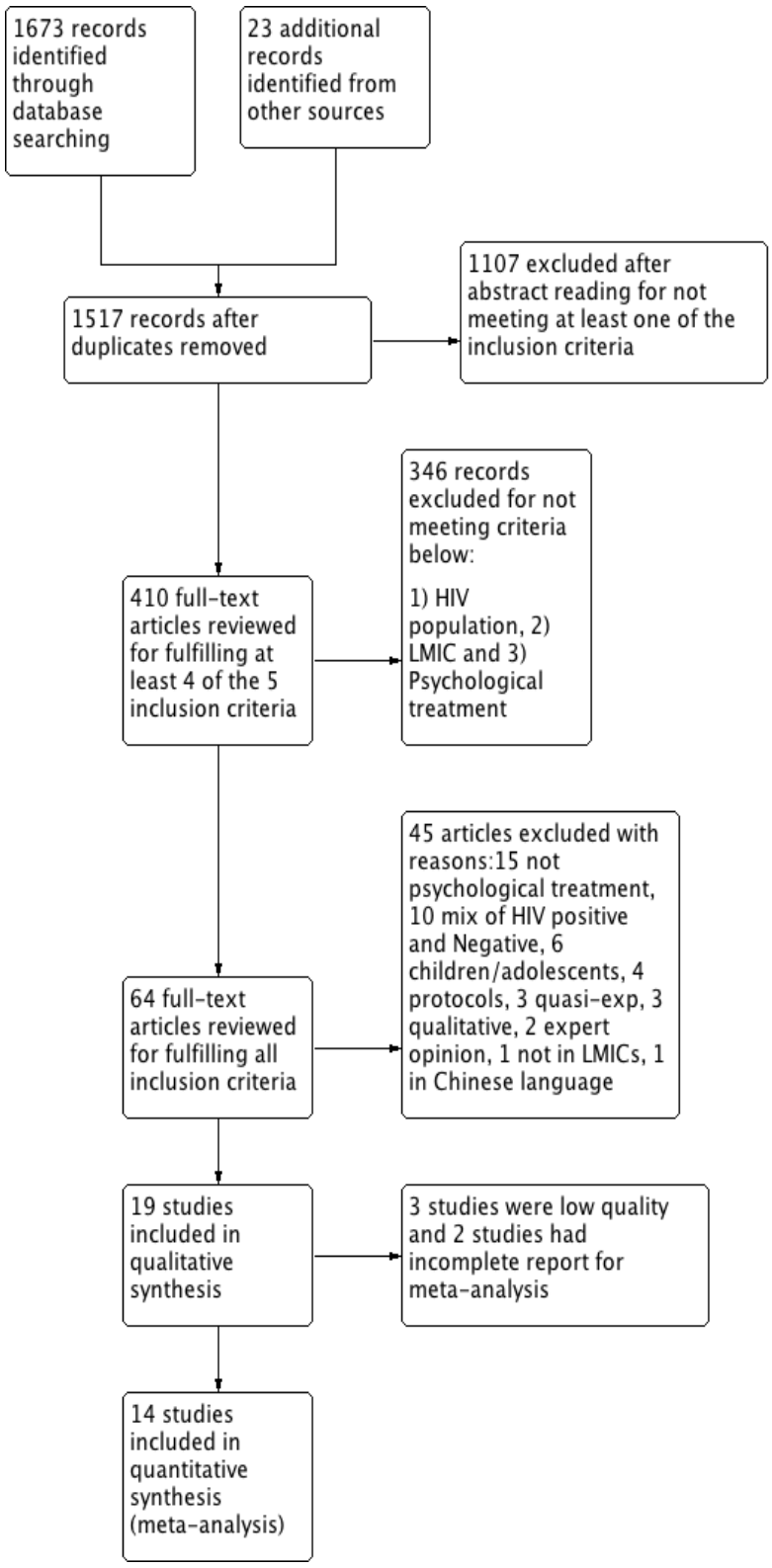

Figure 3. PRISMA flow diagram.

Finally, 19 studies were included for the qualitative review and 14 (74%) were selected for the meta-analysis. Five studies were excluded from the meta-analysis due to poor quality (high risk of bias in two or more domains, three studies) and incomplete reports of results for meta- analysis (two studies). The following studies were excluded for poor quality (1) Jalali (2018) was excluded for not meeting blinding of participants and personnel, blinding of outcome assessment, and other bias criteria; (2) Olley (2006) was excluded for not fulfilling random sequence generation, blinding of participants and personnel, and blinding of outcome assessment; (3) Tshabalala (2011) was excluded for not meeting blinding of participants and personnel and other bias criteria. See Table 4. As shown in Table 2, more than half of the included studies were conducted in sub-Sahara African countries (n=10, 53%). Five studies (26%) were conducted in South Africa and the remaining African studies were done in Kenya, Nigeria, Tanzania, Uganda and Zimbabwe. The remaining studies (n=9, 47%) were conducted in Asia (three in China, two in India, two in Thailand and two in Iran). Of the 19 included studies, 16 (84%) were conducted since 2010 (two studies in 2010, one study in 2011, three studies in 2012, two studies in 2013, four studies in 2014, two studies in 2015 and two studies in 2018). The cumulative number of participants for all included studies was 3255 participants (Intervention=1576, control=1676). Six (32%) studies included only female participants and two (11%) studies included men only. More than three quarters of the participants were female (n=2714, 83%). The smallest and the largest study sample sizes were 16 and 1200 respectively.

2.4.2. Outcome measurement

Of the 19 included studies, 13 studies (69%) assessed depressive symptoms using validated tools and one (5%) study used a locally developed instrument. The remaining five (26%) studies did not provide information on the validation status of the tool they used. The most used instrument to assess depressive symptoms was the Beck Depressive Inventory (BDI-II) – used by six (32%) studies – followed by the Centre for Epidemiological Studies Depression scale (CES-D) which was used by five (26%) studies. Fifteen studies (79%) assessed depressive symptoms as a continuous outcome measure, and the remaining used dichotomous outcome measures. Out of the 19 included studies in the systematic review, 17 (89%) reported depressive symptom scores both at baseline and after treatment. However, two studies reported incomplete quantitative results after treatment. In addition, 10 (53%) studies reported depressive symptoms scores at 6 months after treatment was completed). See Tables 2 and 3.

Table 2. Characteristics of the studies included in the systematic review and meta-analysis (N=19).

Author, year, country	Design & setting	Sample size	Females	Mean age	Intervention	Control	Outcome measure	Measure validation	Assessment point	Therapists	Key result
1. Abas et al – 2018, Zimbabwe (138)	RCT, Hospital	32	21 (66%)	Not reported	**Individual PST** – 6 weekly sessions for 30 to 50 minutes each	Enhanced usual Care Counselling	PHQ-9	Both validated	Baseline, at 6 months	Adherence counsellors and Psychologists	PST is feasible and acceptable. RCT studies with powered sample are needed to show efficacy.
2. Chan et al – 2005, China (139)	Pilot RCT, Health institution	16	0 (0%)	38.2	**Group CBT** – 7 weekly sessions and each lasted for 2 hours	Waitlist control (WLC)	CES-D	No information	Post-treatment	Clinical psychologist	Time-limited group interventions are feasible and effective for HIV infected men
3. Cook et al – 2014, India (140)	Pilot RCT, Health institution	80	23 (29%)	38.4	**Group CBT** –3 monthly session for an hour	Enhanced Standard of Care (ESOC)	BDI-II	Validated in India	Baseline, at 3 and 6 months	Trained Masters level psychologists	Group interventions can be cost-effective and accessible to large number of people at a time.
4. Futterman et al – 2010, South Africa (141)	Pilot Cluster RCT, clinics	160 in 2 clusters	160 (100%)	26.4	**Group CBT** – M2M intervention for 8 sessions, session duration not reported.	Standard care – PMTCT	CES-D	No information	Baseline, at 6 months	Trained mentor mothers living with HIV/AIDS	CBT was successful in reducing depression scores and establishing social support. Mothers were capable to deliver the intervention successfully.
5. Jalali et al – 2018, Iran (142)	RCT, prison	42	0 (0%)	31.8	**Group CBT** – 11 weekly sessions for 90 min each	WLC	BDI-II	Validated in Iran	Baseline, at 3months	Certified schema therapists	Schema-based group CBT helps to reduce depression in prisoner PLWHA. Loss to follow-up was high.
6. Kaaya et al – 2013, Tanzania (143)	RCT, Hospital	331	331 (100%)	26.0	**Group PST** – 6 weekly sessions in closed group of 6-8 individuals, session duration not reported.	Standard care	HSCL-25	Validated in Tanzania	Baseline, at 8 to 10 weeks after	Social worker/psychiatric nurses	Closed and session-limited group intervention is feasible and appeared effective in reducing depression.
7. Li et al – 2010, Thailand (144)	RCT – Hospitals	507	340 (67%)	37.4	**Buddhism framed group CBT** – 13 weekly sessions, session duration not reported.	Standard care	DSST	Validated in Thailand	Baseline, at 6 and 12 months	Unclear	There was no significant reduction of depressive symptoms over 12 moths.
8. Mathiga et al – 2015, Kenya (145)	Clustered RCT, villages	305 in 2 clusters	218 (71%)	Not reported	**Group IPT** – 16 sessions weekly,	Standard care	BDI-II	No information	Baseline, at 6 months	Unclear	Group IPT was effective in reducing major

Author, year, country	Design & setting	Sample size	Females	Mean age	Intervention	Control	Outcome measure	Measure validation	Assessment point	Therapists	Key result
					session duration not reported.						depressive and suicide symptoms in PLWHA
9. Molassiotis et al – 2002, China (146)	Pilot RCT, Health institution	35	3 (9%)	39.1	**Group CBT** and **peer support counselling** – 12 weekly sessions for 2 hours each	Standard care	POMS	Validated in China	Baseline, at 3 and 6 months	Qualified nurses experienced in counselling	CBT could have short-term effect. PSC group showed worsening of symptoms at post-treatment but dramatically improved at follow-up assessment.
10. Nakimuli-Mpungu et al – 2015, Uganda (147)	RCT, HIV-care centres	109	46 (42%)	44.7	**Group Support Psychotherapy** @ – 8 weekly sessions for 2 to 3 hours each	Group HIV Education (GHE)	SRQ-20	Validated in Uganda	Baseline, at post-treatment, at 6 months	Mental health workers with a mental health diploma or degree	There was significant reduction of symptoms at the follow-up assessment. GSP is highly effective for depression, functioning, social support and self-esteem.
11. Nyamathi et al – 2012, India (148)	Pilot cluster RCT, rural villages	68 in 2 clusters	68 (100%)	31.2	**Individual Behavioural Therapy** – 6 sessions, session duration not reported.	Standard care	CES-D – 20	Validated in India	Baseline, at 6 months	Trained women who finished at least high school	There was substantial degree of reduction in depressive symptoms in the intervention group while it increased in the control group.
12. Olley – 2006, Nigeria (149)	Pilot RCT, hospital	67	35 (56.5%)	28.6	**Individual Psycho-education** – 4 weekly sessions for 1 hour each	Enhanced care	BDI	Validated in Nigeria	Baseline, at 8 weeks	Unclear	The result showed encouraging efficacy of psychoeducation programme in reducing social and psychological problems of PLWHA.
13. Peltzer et al – 2012, South Africa (95)	RCT, Hospital	152	99 (65%)	36.9	**Group CBT** – 3 monthly sessions for 1 hour each	Standard care	BDI-II	No information	Baseline, at 3 months follow-up	Lay health workers and adherence counsellors	No significant intervention effect found. Lay health workers may deliver interventions only if they get advanced skill trainings.
14. Petersen et al – 2014, South Africa (150)	Pilot RCT – public clinic	34	25 (74%)	Not reported	**Group IPT** – 8 weekly sessions, session duration not reported.	Standard care	PHQ-9	Validated in South Africa	Baseline, at 3 months	Lay counsellors	Group IPT for depression for PLWHA can potentially be delivered effectively by

Author, year, country	Design & setting	Sample size	Females	Mean age	Intervention	Control	Outcome measure	Measure validation	Assessment point	Therapists	Key result
											lay HIV counsellors. Larger trial is needed.
15. Richter et al – 2014, South Africa (151)	Cluster RCT, 8 clinics	1200 in 2 clusters	1200 (100%)	26.5	**Group Psycho-education** using M2M programme – 8 weekly sessions, session duration not reported.	Standard care	GHQ	Validated in South Africa	Baseline, Post-treatment	Trained peers (they received training for 2 months)	Attrition rate was very high in both groups. The intervention brought modest improvement in maternal and child outcomes.
16. Ross et al – 2013, Thailand (152)	RCT, community	40	40 (100%)	26.6	**Telephone call counselling** – for 2 months, 1 to 3 times a week, each call lasted 15-30 minutes.	Standard care	CES-D	Validated in Thailand	Baseline, at 1 month, 2 months	Registered nurses	Depressive symptoms decreased over time in the intervention group. Telephone support could be an option but doesn't work for everyone.
17. SeyedAlinaghi et al – 2012, Iran (153)	RCT, Hospital	245	53 (31%)	35.1	**Group Mindfulness Based Stress Reduction** – for 8 weekly sessions, session duration not reported.	Education and support group	SCL-90R	Validated in Iran	Baseline, at 3, 6, 9 and 12 months	Mindful-Based Stress Reduction Trained psychologist	Depressive symptoms reduction was observed but it didn't sustain after 6 months. The intervention could have potential to alleviate symptoms.
18. Tshabalala – 2011, South Africa (154)	Pilot RCT, Hospital	20	20 (100%)	Not reported	**Individual CBT** – 8 weekly sessions, session duration not reported.	WLC	BDI-II	No information	Baseline and at post-treatment	Unclear	Depression score decreased significantly in the experimental group. Similarly, positive coping increased after the therapy.
19. Williams et al – 2014, China (155)	RCT – Hospital	110	32 (29%)	37.5	**Individual Psycho-education** – 9 home visits in 3 months, session duration not reported.	Standard care	CES-D	Validated in China	Baseline, at 6 and 12 months	Nurses and peer educators	Home visit or off-site visits are time consuming and difficult to arrange. Future studies should address both depression and adherence.

Group Support Psychotherapy @ is developed from three theories: cognitive behaviour theory, social learning theory and the sustainable livelihood framework. "No information" regarding whether the instrument is validated in the local context or not. **Acronyms:** BDI-I or BDI-II (Beck Depression Inventory – I/II), CES-D (Centre for Epidemiological Studies – Depression Scale), DSST (Depressive Symptomatology Screening Test), GHQ (General Health Questionnaire), HSCL-25 (Hopkins Symptom Checklist - 25), M2M (Mother to Mother), PHQ-9 (Patient Health Questionnaire - 9), POMS - depression module (Profile Of Mood State – depression module), RCT (Randomised Controlled Trial), (SA= South Africa), SCL-90R (Symptom Checklist – 90 Revised), SRQ-20 (Self Report Questionnaire - 20), SSQ-14 (Shona Symptoms Questionnaire)

Table 3. Outcomes of the studies included in the meta-analysis (n=14).

Author, Year, Country	Tool		Intervention			Control			Effect size by SMD or RR	
			N (dropout)	Baseline (mean, SD)	Follow-up (mean, SD)	N (dropout)	Baseline (Mean, SD)	Follow-up (Mean, SD)	Effect size	95% CI
Abas et al – 2018, Zimbabwe (138)	PHQ-9*		14 (1)	13.8 (2.2)	3.1 (3.1)	18 (3)	9.2 (3.3)	5.7 (3.9)	-0.71	-1.43, 0.01
Chan et al – 2005, China (139)	CES-D*		6 (no dropout)	16.67 (6.59)	9.17 (5.31)	7 (no dropout)	13.57 (9.50)	13.71 (9.88)	-0.51	-1.64, 0.60
Futterman et al – 2010, South Africa (141)	CES-D*		40 (37)	14.0 (6.6)	5.6 (4.9)	31 (not reported)	9.0 (6.4)	5.0 (4.0)	0.13	-0.34, 0.60
Kaaya et al – 2013, Tanzania (143)	HSCL-25# Cut-off for depression was ≥1.06		97 (no dropout)	70 (71.0%)	58 (60.0%)	91 (no dropout)	68 (75.0%)	66 (73.0%)	0.82	0.67, 1.01
Mathiga et al – 2015, Kenya (145)	BDI-II*		152 (1)	15.0 (11.0)	5.4 (7.1)	153 (3)	17.3 (11.1)	24.2 (8.2)	-2.44	-2.74, -2.15
Molassiotis et al – 2002, China (146)	POMS* – depression module	CBT	10 (not reported)	15.1 (6.2)	3 mo = 14.0 (6.9) 6 mo = 14.1 (5.1)	26 (not reported)	17.7(12.1)	3 mo = 19.6 (10.5) 6 mo = 19.3 (11.3)	-0.57 0.51	-1.31, 0.18 -1.25, 0.23
		PSC	10 (not reported)	20.6 (14.1)	3 mo = 29.3 (4.9) 6 mo = 20.9 (11.9)			3 mo = 19.6 (10.5) 6 mo = 19.3 (11.3)	0.98 0.14	0.21, 1.74 -0.59, 0.87
Nakimuli-Mpungu et al – 2015, Uganda (147)	SRQ-20*		57 (7)	15.39 (3.40)	Post-treatment = 5.48 (0.48) After 6mo=3.20 (0.45)	52 (3)	15.57 (3.28)	Post GHE = 5.67 (0.48) After 6 mo = 5.70 (0.45)	-0.39 -5.52	-0.77, -0.01 -6.35, -4.68
Nyamathi et al – 2012, India (148)	(CES-D) – 20*		34 (no dropout)	Mean difference = -16.85 (9.6)		34 (no dropout)	Mean difference = 10.56 (12.7)		-2.41	-3.04, -1.77
Peltzer et al – 2012, South Africa (95)	BDI-II*		76 (3)	26.8(22.2)	Post-treatment = 21.5(21.3)	76 (1)	25.5 (23.0)	Post-usual care = 21.3 (21.6)	0.03	0.29, 0.35
Petersen et al – 2014, South Africa (150)	PHQ-9*		17 (3)	15.47 (4.46)	6.94 (4.14)	17 (1)	15.18 (5.46)	11.06 (4.58)	-0.92	-1.63, -0.21
Richter et al – 2014, South Africa (151)	GHQ# Cut-off for depression was ≥7		544 (167)	80 (14.7%)	20 (5.3%)	656 (190)	89 (13.6%)	57 (12.2%)	0.42	0.26, 0.70

Author, Year, Country	Tool	Intervention			Control			Effect size by SMD or RR	
		N (dropout)	Baseline (mean, SD)	Follow-up (mean, SD)	N (dropout)	Baseline (Mean, SD)	Follow-up (Mean, SD)	Effect size	95% CI
Ross et al – 2013, Thailand (152)	CES-D*	20 (not reported)	25.3 (11.63)	2 mo after treatment = 18.9 (8.63)	20 (not reported)	18.4 (8.85)	2 mo after treatment = 21.2 (10.26)	-0.24	-0.86, 0.38
Seyed Alinaghi et al – 2012, Iran (153)	SCL-90R*	120 (33 not given adequate treatment)	109.3 (64.8)	Post-treatment = 97.5 (60.7) At 6 mo = 106.3 (61.8)	125 (39 not given adequate treatment)	109.2 (59.2)	Post-treatment = 109.4 (59.1) At 6 mo = 109.7 (60.8)	-0.20 -0.06	-0.50, 0.10 -0.36, 0.24
Williams et al – 2014, China (155)	CES-D# Cut-off for depression was ≥16	55 (3)	32 (58%)	At 6 mo = 28 (51%)	55 (13)	42 (76%)	At 6 mo = 37 (67%)	0.76	0.55, 1.04

KEYs: continuous outcome measure (*), categorical outcome measure (#), Negative Standard Mean Difference (SMD) favours experiment group, but exception with Risk Ratio (RR). **Acronyms:** BDI-I or BDI-II (Beck Depression Inventory – I/II), CES-D (Centre for Epidemiological Studies – Depression Scale), GHE (Group HIV Education), GHQ (General Health Questionnaire), HSCL-25 (Hopkins Symptom Checklist - 25), mo (month), PHQ-9 (Patient Health Questionnaire - 9), POMS - depression module (Profile Of Mood State – depression module), RR (Risk Retio), SCL-90R (Symptom Checklist – 90 Revised), SRQ-20 (Self Report Questionnaire - 20), SSQ-14 (Shona Symptoms Questionnaire), SMD (Standard Mean Difference)

Table 4. Studies excluded from the meta-analysis (n=5).

Author, Year, Country	Tool	Intervention			Control			Reason for exclusion in the meta-analysis
		N (dropout)	Baseline (mean, SD)	Follow-up (mean, SD)	N (dropout)	Baseline (Mean, SD)	Follow-up (Mean, SD)	
Cook et al – 2014, India (140)	BDI-II[#] Cut-off for depressed was ≥14	34 (3)	9 (26%)	Incomplete report	46 (4)	11 (24%)	Incomplete report	Incomplete report
Jalali et al – 2018, Iran (142)	BDI-II*	21 (not reported)	25.04 (7.22)	12.14 (6.52)	21 (not reported)	18.14 (9.32)	19.57 (8.36)	Poor quality
Li Li et al – 2010, Thailand (144)	Thai 15-item screening tool[*]	260 (not reported)	12.2 (8.3)	Incomplete report	247 (not reported)	12.4 (8.0)	Incomplete report	Incomplete report
Olley – 2006, Nigeria (149)	BDI[*]	34 (2)	19.0 (6.4)	Post-treatment = 18.1 (1.2) Follow-up = 5.7 (1.5)	33 (3)	17.0 (2.4)	Post-usual care = 18.1 (3.7) Follow-up = 14.2 (2.5)	Poor quality
Tshabalala – 2011, South Africa (154)	BDI-II*	10 (not reported)	28.1 (12.7)	-19.2 (9.8)	10 (not reported)	24.3 (6.2)	-0.6 (5.9)	Poor quality

KEYs: continuous outcome measure (*), categorical outcome measure (#), Negative Standard Mean Difference (SMD) favours experiment group, but exception with Risk Ratio (RR). **Acronyms:** BDI-I or BDI-II (Beck Depression Inventory – I/II), CES-D (Centre for Epidemiological Studies – Depression Scale), GHE (Group HIV Education), GHQ (General Health Questionnaire), HSCL-25 (Hopkins Symptom Checklist - 25), mo (month), PHQ-9 (Patient Health Questionnaire - 9), POMS - depression module (Profile Of Mood State – depression module), RR (Risk Retio), SCL-90R (Symptom Checklist – 90 Revised), SRQ-20 (Self Report Questionnaire - 20), SSQ-14 (Shona Symptoms Questionnaire), SMD (Standard Mean Difference).

2.4.3. Intervention characteristics

The type of psychological treatments used were as follows: eight (42%) studies used CBT, five (26%) studies used psycho-education/counselling, two (11%) studies used IPT, two (11%) studies used PST. Of the total studies included for the systematic review, 12 (63%) used group psychological treatment (group-based) approaches. In terms of therapists, seven (37%) used trained non-specialists (lay counsellors) to deliver treatments. After excluding the study using a phone call counselling (phone call was made any time as needed), mean, median and mode of number of sessions was eight for all, ranging from four to 16 sessions. Six studies (32%) carried out their intervention for eight weekly sessions. Half (50%) of the studies reported duration of sessions for each intervention. The shortest session was 30 minutes and the longest was 180 minutes. The mean duration of sessions was 86 minutes, and the mode and the median were 60 minutes. See Table 2.

2.4.4. Quality of included studies

Of the 19 studies included in this review and meta-analysis, 16 (84%) had at least one unclear domain with respect to the Cochrane collaboration risk of bias checklist and 10 (53%) studies had at least one domain with a high risk of bias. Three studies were of very poor quality and two studies had incomplete data for analysis. See Figure 4.

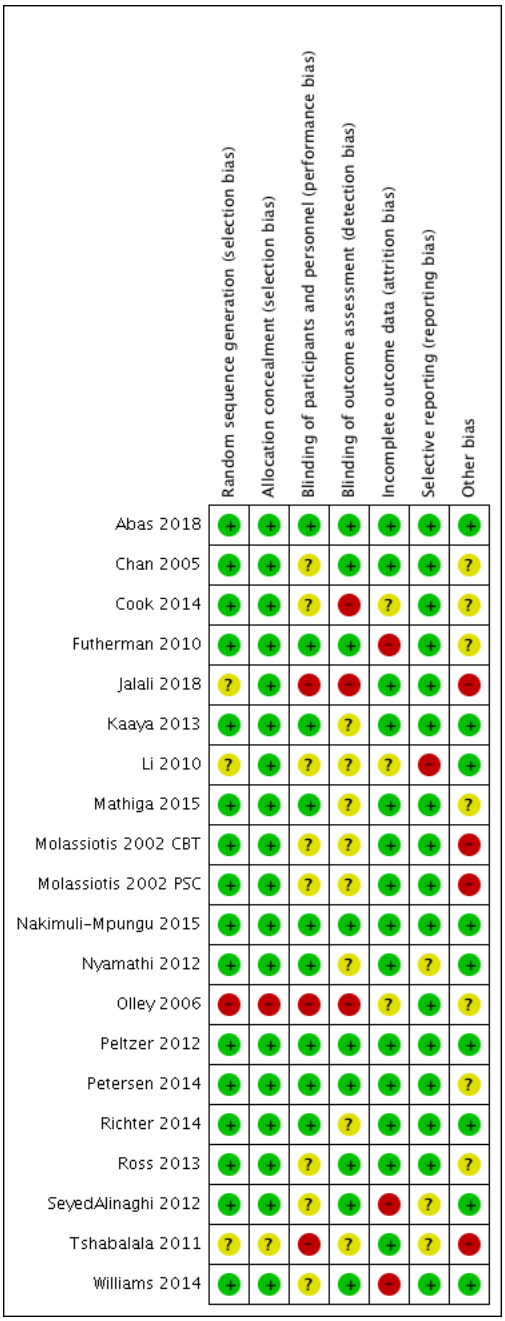

Figure 4. Risk of bias of the studies included in the systematic review and meta-analysis (N=19).

2.4.5. Meta-analysis and effect size

Of the 14 (74%) studies included in the meta-analysis, 11 (79%) reported mean depressive symptoms scores along with the standard deviation, and three (21%) reported the proportion of participants who scored above and below the cut-off point. To manage this, a sub-group analysis was done for continuous and dichotomous outcomes independently. Pooled effect size of trials that used continuous outcomes was -0.61 (n=12; CI: -1.24, 0.02; I^2=95%) at the post-treatment assessment (soon after the end of the treatment). The effect sizes at six months follow-up was analysed to determine whether treatment effects are sustainable. Figure 5 presents effect sizes of studies at the six months follow-up assessment and their pooled effect size was -1.41 (n=8; 95%CI: -2.54, -0.28; I^2 = 98%). See figures 5, 6, 7.

The effect sizes in the meta-analysis ranged from none to large. The effect size at the post-treatment was large (smd>0.5) in eight (60%) studies. The largest effect size at the post-treatment assessment was found for a trial evaluating group IPT (smd = -2.44; 95% CI: -2.74, -2.15), and from a trial that evaluating locally developed peer-support counselling (smd = -2.41; 95%CI: -3.04, -1.77). See figure 8.

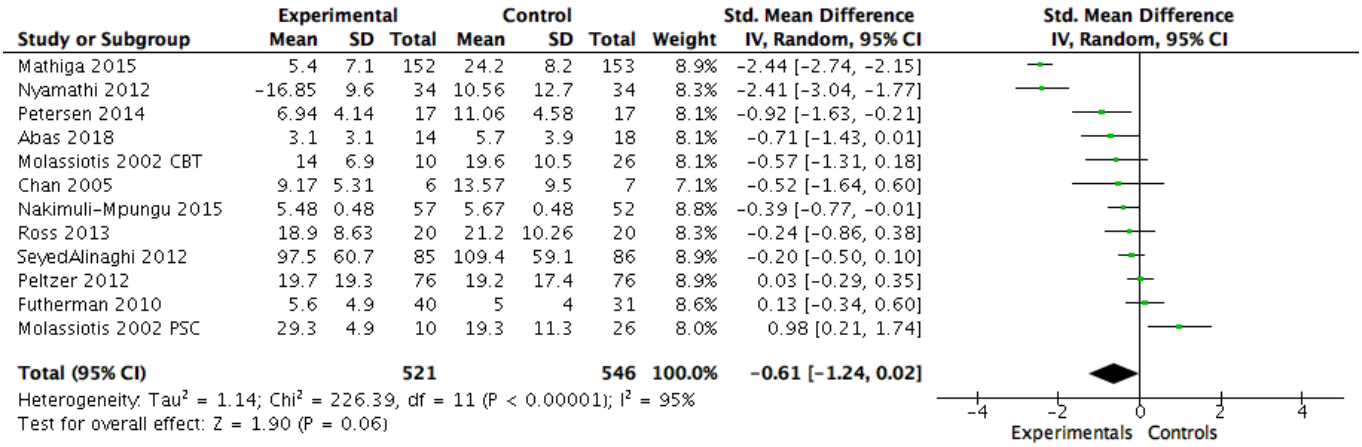

Figure 5. Forest plot of effect sizes for continuous outcome measures at the post-intervention (n=12).

Molassiotis 2002 CBT and Molassiotis 2002 PSC are from the same study that compared CBT and PSC with the same control group.

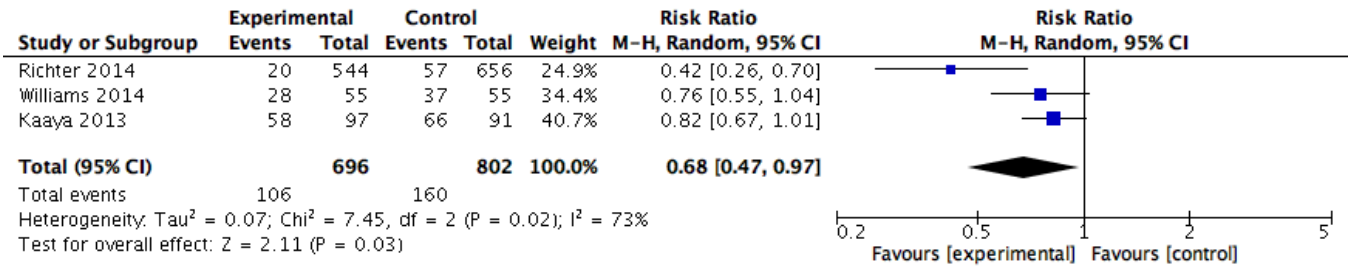

Figure 6. Forest plot of effect sizes for dichotomous outcome measures at the post-intervention (n=3).

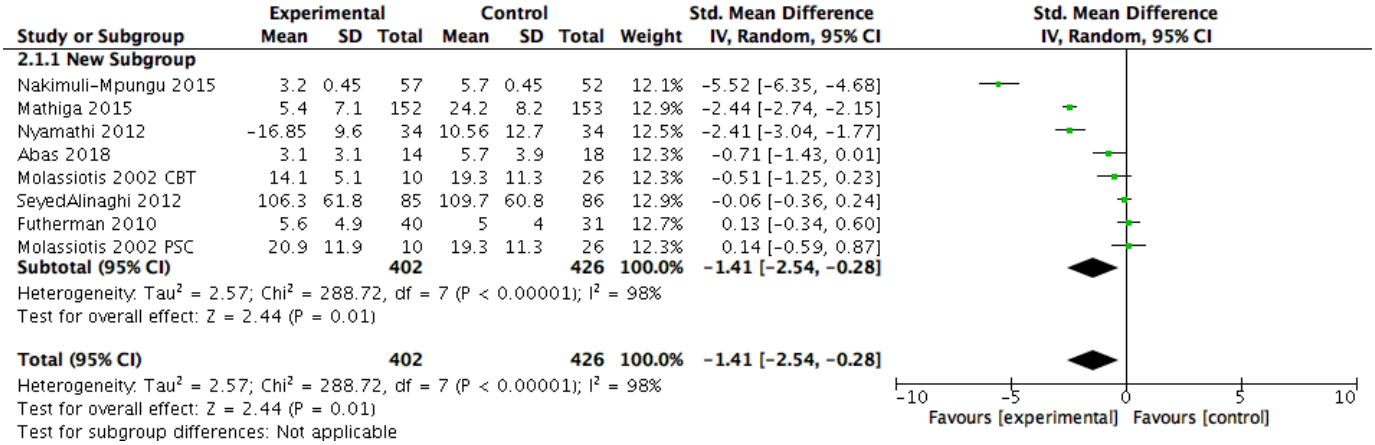

Figure 7. Forest plot of effect sizes for continuous outcome measures at six months follow-up (n=8).

Molassiotis 2002 CBT and Molassiotis 2002 PSC are from the same study that compared CBT and PSC with the same control group.

The pooled effect sizes by treatment type are presented in Figure 8. The pooled effect size of CBT trials was small (n=4; smd = -0.03; 95%CI: -0.27, 0.21). However, the pooled effect size of IPT trials was larger (smd= -1.72; n=2; 95%CI: -3.21, -0.23; I^2=93%) than CBT trials. Furthermore, the pooled effect of trials that used peer-support counselling was -1.14 (n=2; 95%CI: -3.63, 1.35; I^2 = 96%).

A sub-group analysis by format of treatment delivery was conducted. The pooled effect size of group-based trials was -1.04 (n=9; 95%CI: -2.02, -0.05; I^2 = 97%). Similarly, the pooled effect size of individual-based trials was -1.12 (n=3; 95%CI: -2.46, 0.22; I^2 = 92%). The forest plot of pooled

effect sizes by format of delivery is presented in Figure 9. Figure 10 presents a forest plot of effect sizes by proficiency of therapists.

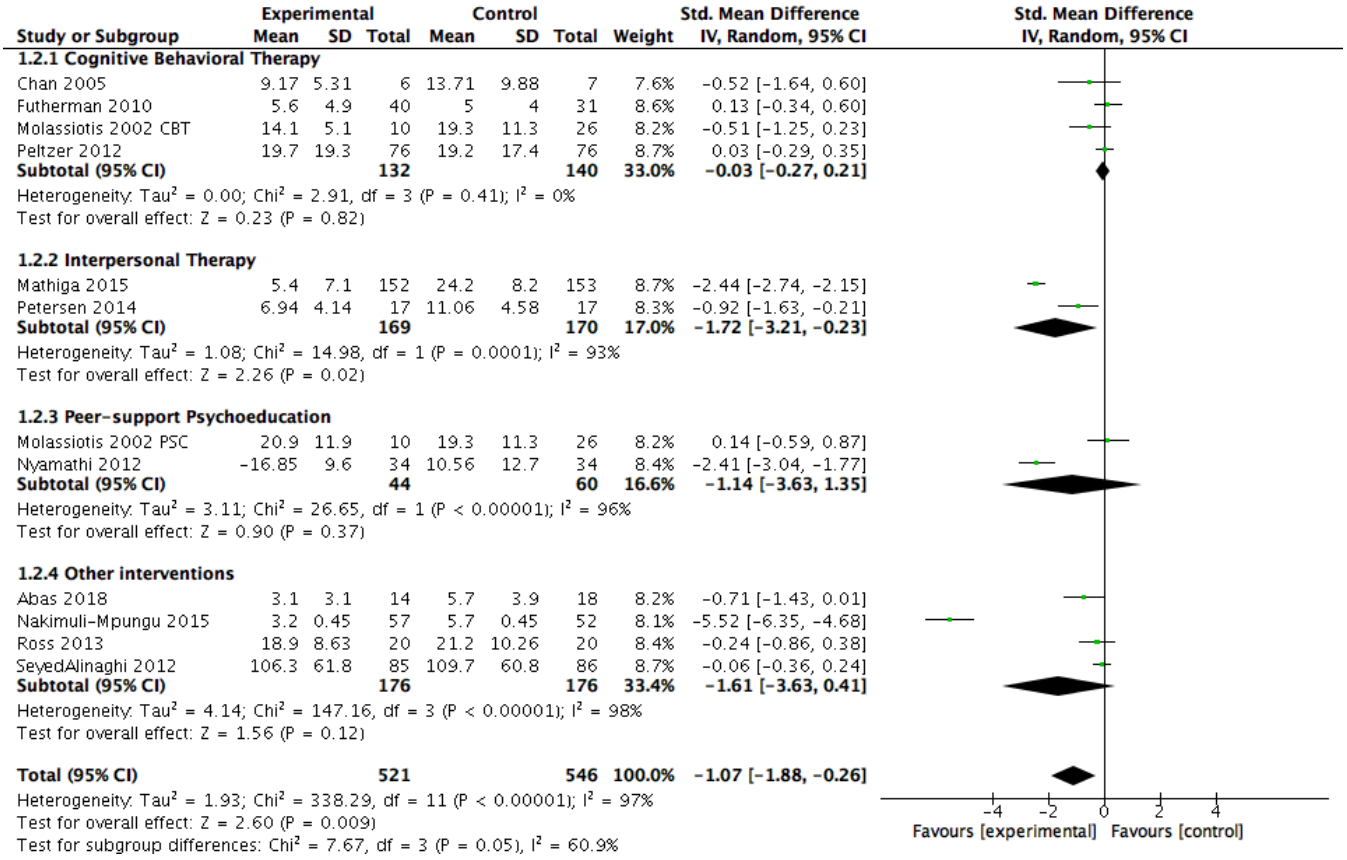

Figure 8. Forest plot of effect sizes by type of psychological treatment for continuous outcome measures (n=12).

Molassiotis 2002 CBT and Molassiotis 2002 PSC are from the same study that compared CBT and PSC with the same control group.

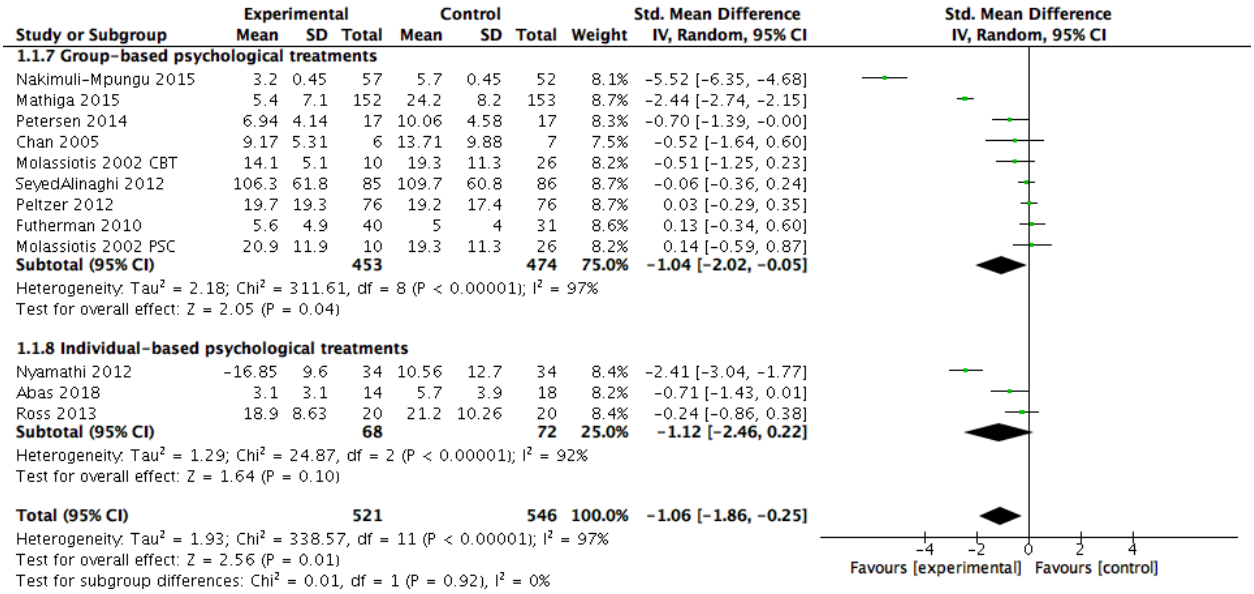

Figure 9. Forest plot of effect sizes by format of delivery for continuous outcome measures (n=12).

Molassiotis 2002 CBT and Molassiotis 2002 PSC are from the same study that compared CBT and PSC with the same control group.

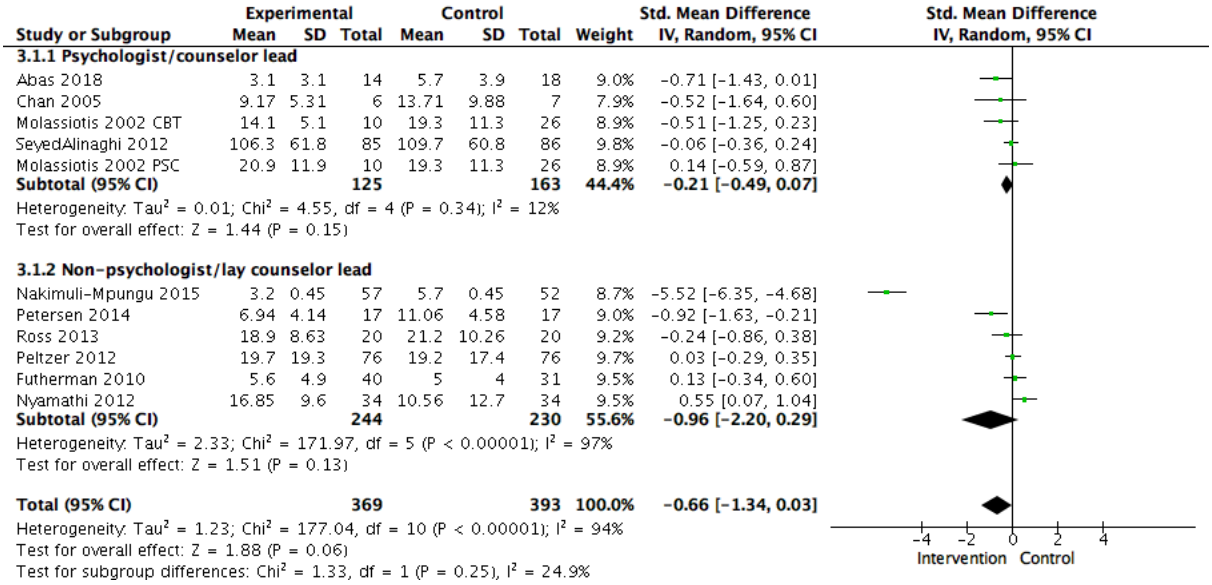

Figure 10. Forest plot of effect sizes by level of qualification of counsellors (n=11).

Molassiotis 2002 CBT and Molassiotis 2002 PSC are from the same study that compared CBT and PSC with the same control group.

A sub-group analysis was conducted by region where studies were conducted. Studies from Africa showed a larger pooled effect size (smd = -1.51; n=6, 95%CI: -2.90, -0.13; I^2 = 98%) than studies from Asia (smd = -0.60, n=6, 95%CI: -1.36, 0.17; I^2 = 89%). Another sub-group analysis by duration of treatment was conducted using eight sessions as the cut-off point since the mean number of sessions was eight. The studies that used eight sessions or less showed -1.12 (n=9; 95%CI: -2.00, -0.25; I^2 = 96%) pooled effect size. The pooled effect size of the group of studies that used nine or more sessions was -0.70 (n=3; 95%CI: -2.84, 1.44; I^2=97%). See figures 11 and 12.

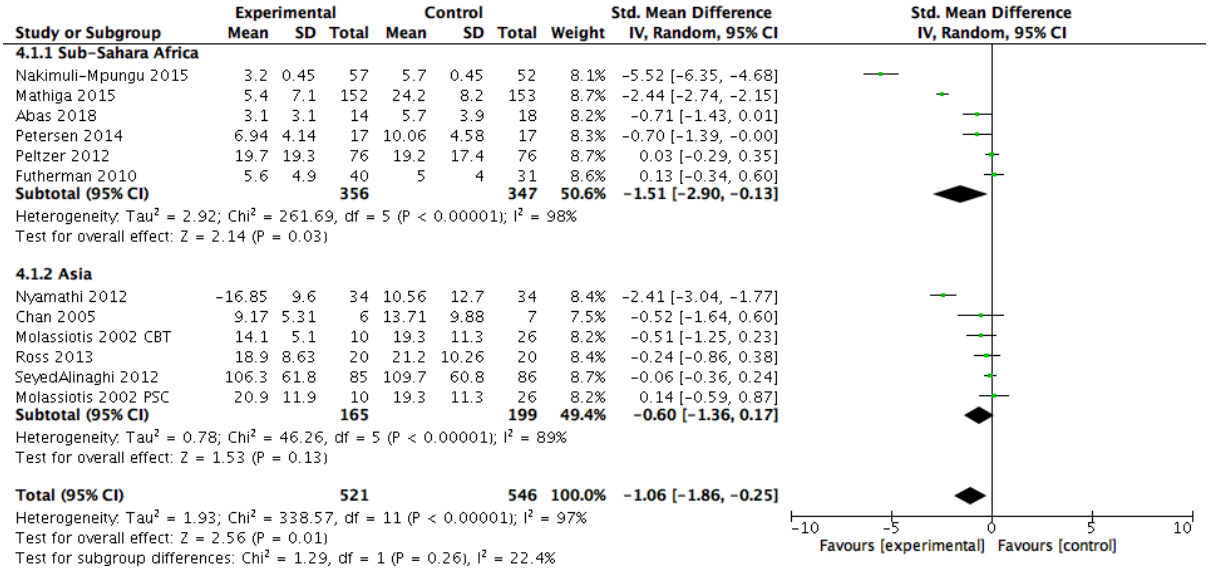

Figure 11. Forest Plot of effect sizes by region.

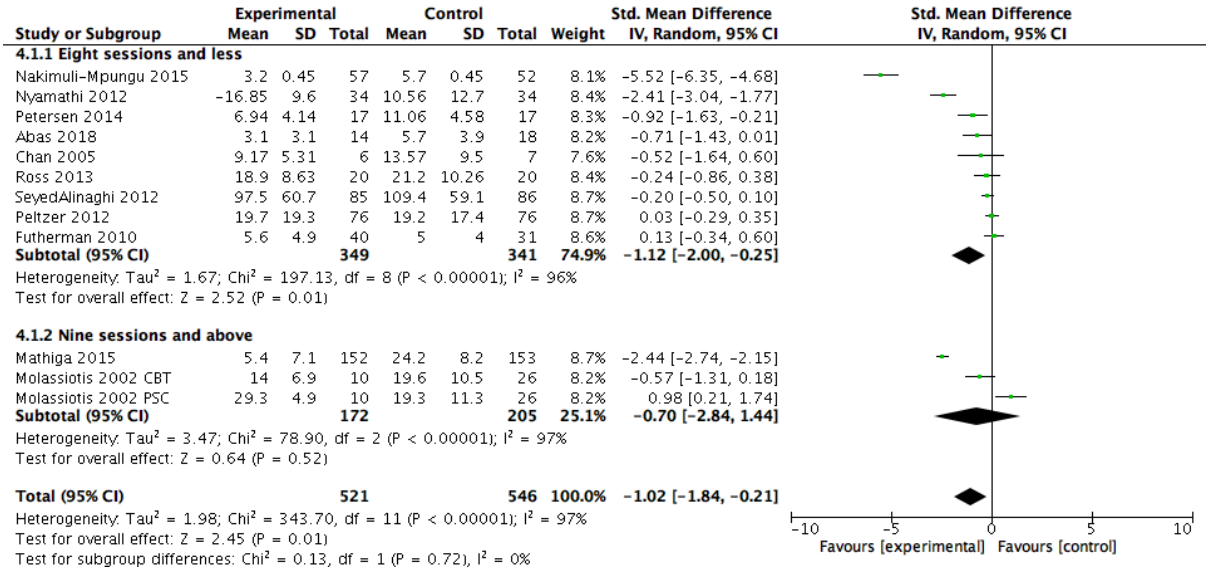

Figure 12. Forest plot of effect sizes by number of sessions.

A funnel plot in Figure 13 shows that large studies are evenly scattered in- and outside the inverted funnel. It shows that there is relative closeness in study sizes, but the effect estimate varies across the studies. The funnel plot is asymmetric because most studies lay on the upper right side of the diagram. It suggests that few large and highly significant studies were missed on the upper left side of the diagram. The Egger's test was conducted to look at the source of the asymmetry. The Egger test presents p=0.71 (n=12; coef. = 0.96; 95%CI: -4.10, 6.02) which indicates no publication bias.

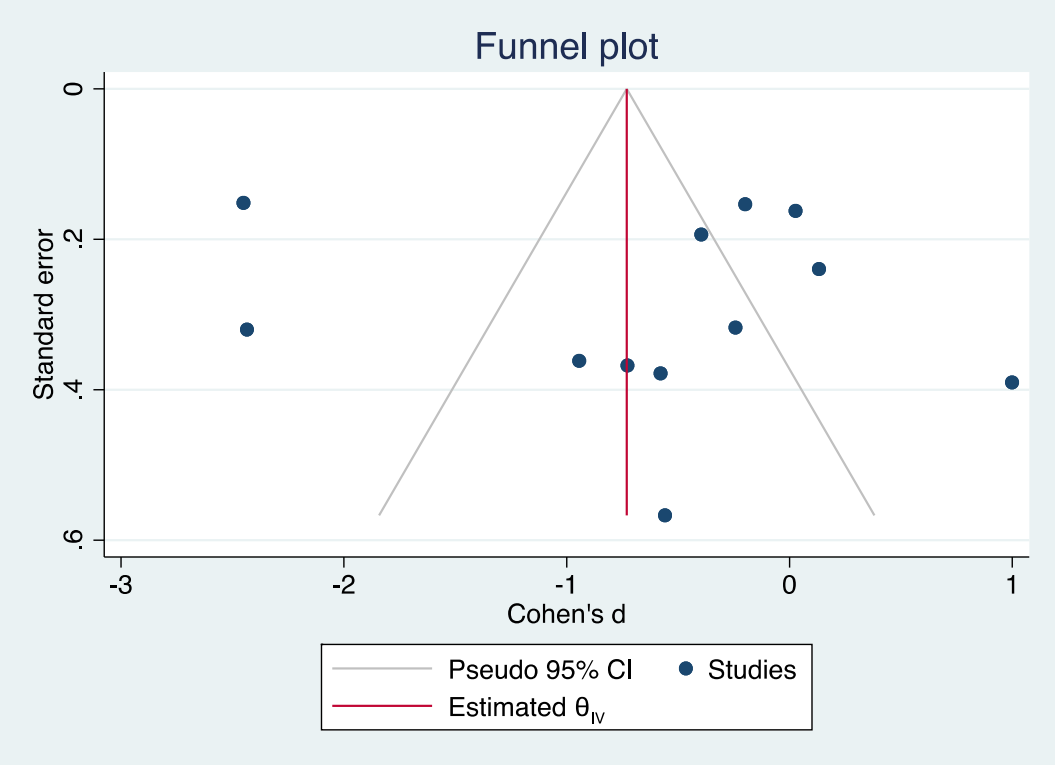

Figure 13. Funnel plot of effect sizes for continuous outcome measures at post-treatment.

2.5. Discussion

This systematic review and meta-analysis showed that a variety of psychological treatment trials have been conducted in LMICs. These trials are diverse and took place across a range of African and Asian countries. One third of these trials evaluated CBT either in a group or individual format and the remaining used Peer-support counselling, IPT, PST and Group Support Psychotherapy (GSP). All the included studies reported reduction in depressive symptoms from the baseline even though the reduction is not significant in some trials when compared to the control group. While acknowledging their limitations, most studies encouraged the use of psychological treatments for depressive symptoms in HIV populations and they suggested further studies be conducted.

Results from our review are consistent with other findings from LMICs (133). Several studies from Africa support the effectiveness and acceptability of group-based IPT, PST and peer-support counselling for treatment of depressive symptoms in HIV-affected communities (90, 96, 156-158). A pilot trial from rural South Africa reduced depressive symptoms over 12 sessions of group IPT using trained community health workers (96). In Uganda researchers were able to show high acceptability of group IPT with high reduction of depressive symptoms (90, 92). Similarly, in Zimbabwe clinically significant reduction of depressive symptoms was achieved over six sessions of group PST delivered by peer counsellors (156). Locally adapted or developed psychological treatments are becoming appropriate, acceptable and effective in African cultures (141, 151). For instance, the Friendship Bench programme using PST in Zimbabwe (159) and culture-sensitive GSP developed in Uganda (147, 159) have become an acceptable and effective treatment approach for common mental disorders provided by peer-counsellors.

Even though the effect size across the studies varies from very low to high, the effect size at the six months follow-up increased significantly compared to the one at the post-treatment assessment (immediately after intervention). However, two studies reported a 12 months follow-up result which showed that the depressive symptoms returned to the baseline level indicating that the effect of the intervention failed to be sustained for 12 months (153, 155).

Group-based psychological treatment trials were effective in reducing depressive symptoms except for two group-based CBT trials (95, 141). A trial from Uganda which used GSP (147) and a trial from South Africa which used group IPT (150) had higher effect sizes compared to other trials using group CBT. These findings are supported by another meta-analysis and two further trials. The meta-analysis by van der Heijden et al (2017a) of group psychological treatments found a small effect size for group CBT. Two trials from non-HIV/AIDS populations found high effect sizes in reducing depressive symptoms from group-based IPT and PST therapies (90, 156). It is difficult to compare individual-based and group-based therapies in terms of acceptability as most trials, especially individual-based interventions, did not report findings (such as drop outs) related to it. In terms of pooled effect size, there was no statistical difference between group-based and individual-based treatments. On the surface this may indicate that neither approach is more effective than the other. However, it is crucial to take into consideration issues of confidentiality, cost and acceptability when considering the format of delivery. Furthermore, the small number of studies and the high level of heterogeneity indicate the need for further research in this area, testing and comparing treatment formats and types.

In this meta-analysis, there was no significant difference in effect size between the use of psychologists and non-psychologists (lay counsellors). Emerging task shifting studies from LMICs have produced evidence that encourages the use of trained and supervised lay counsellors to fill the human resource gap in low-income settings (158, 160-162). A study from five LMICs (Ethiopia, India, Nepal, South Africa and Uganda) indicated that a task-sharing approach in delivering different interventions was feasible and it was acceptable to service providers (163). A task shifting study from Brazil (164) examined the capability of community health workers to deliver IPT in primary health care settings. This pragmatic trial found that community health workers delivered the intervention successfully. Evidence from these studies showed that trained lay counsellors who have at least high school education can deliver psychological treatments effectively under supervision. Contrarily, most CBT trials (five of the seven CBT trials reviewed) used psychologists as therapist and the number of sessions used range from four to 13 which could be a costly treatment for LMICs. Although most CBT trials used qualified therapists, they showed a lower pooled effect size. This low effect size could be related to factors other than the effectiveness of CBT per se. For example, factors such as the therapist's qualification, cultural acceptability of the intervention and whether the therapists culturally competent may influence the outcomes. These would need to be investigated further before coming to any conclusion.

A sub-group analysis by type of psychological treatment shows larger effect sizes using IPT and PST, and smaller or no effect sizes for CBT. However, there was high heterogeneity both among and between types of psychological treatment, limiting the conclusions that can be drawn from these comparisons. This study did not look for effect modification by type of psychological intervention and there were only 2 IPT trials, so the apparent differences may not be statistically significant. Although heterogeneity was high, large effect sizes were observed at the post-treatment assessment (immediately after the intervention) for the trials using peer-support counselling, IPT and PST. Statistical testing the differences between intervention types with one treatment type as a reference category may be inappropriate to compare treatment types and withdrawn any inference that specific treatment types are necessarily more effective than the others. However, there are other well documented studies that support the efficacy of these psychological treatments with the HIV/AIDS population (132, 165-167). In one study the effect size returned to its baseline state at the 12^{th} month evaluation (153) – which may indicate that continuous support is needed after completion of psychological treatments to sustain the reduction of depressive symptoms beyond 12 months.

CBT trials with a high number of sessions that were delivered by non-psychologists were less effective (142, 144, 146) than IPT trials (145, 150). Furthermore, loss to follow-up was high in psychological treatments requiring a high number of sessions (142). CBT delivered by lay health workers may not be effective as it requires advanced skill training (95). This indicates the need for psychological treatments that are effective with a few numbers of sessions and can be delivered by trained lay counsellors.

The findings presented on the funnel plot suggest that large and statistically significant studies are missing in the evidence base. It is implausible that large and highly significant studies remain unpublished. Thus, publication bias is unlikely to be the source of asymmetry for the funnel plot. This is in agreement with the result of the Egger's test that indicates no publication bias. Therefore, the asymmetry and effect variation across studies in this funnel plot could be due to methodological heterogeneity (rather than publication bias) such as difference in type of treatments, in number of sessions, and difference in treatment of control groups, with some studies using enhanced usual care while others using only usual care. These reasons for asymmetry of the funnel plot could also indicate the high levels of heterogeneity for each sub-group meta-analysis.

Overall, based on this systematic review and meta-analysis result, the use of GSP, IPT, PST and peer-support counselling seem to be the most effective in reducing depressive symptoms in PLWHA in LMICs.

Limitations

This systematic review and meta-analysis relied on the results obtained from studies ranging from low to high risk of bias. The exclusion of the five studies from the meta-analysis is a limitation although they were of poor quality and including them would have compromised the quality of the analysis. Not having an independent person to screen abstracts may have resulted in missed identification of important articles, therefore it should be considered as one of the limitations of this study. False negative and false positive significant tests increase in likelihood rapidly as more sub-group analyses are performed. Therefore, we understand that the sub-group analysis with less than four studies per category may be under-powered to detect differences. Our approach to this sub-group meta-analysis was to apply a set of *a priori* criteria namely type of intervention, treatment approach/format of delivery, and therapist type. In some of the sub-groups so defined the number of studies is less than four but this does not apply to all sub-groups within each sub-group meta-analysis. Therefore, results from the sub-group analysis should be interpreted with

caution as differences within different types of psychological treatment, may be as big as differences between types of psychological treatments. Variation in the instruments used and difference in cut-off points (the use of general population cut-off for HIV populations) across studies is another limitation of this meta-analysis. Furthermore, there was heterogeneity across the studies and the meta-analysis results should be interpreted with caution. In this study trials published in languages other than English were excluded.

2.6. Conclusion

This systematic review and meta-analysis found that psychological treatments are effective in reducing depressive symptoms for PLWHA in LMICs. The meta-analysis results indicated that GSP, IPT, PST, peer-support counselling seem effective in reducing depressive symptoms. Furthermore, both group- and individual-based psychological treatments displayed similar effectiveness in reducing depressive symptoms. Although CBT was a commonly used psychological treatment, it showed modest effectiveness in reducing depressive symptoms for PLWHA in LMICs. Psychological treatments that are simple to deliver by trained lay counsellors, and that could bring significant reduction of depressive symptoms with few numbers of sessions should be encouraged in LMICs. We recommend that future trials follow the Cochrane risk of bias assessment criteria to ensure high quality reporting. We suggest future studies should examine a number of mechanisms which may influence the outcomes of psychological treatments for this population, including delivery mechanisms, cognitive, affective and behavioural mechanisms of change, and strengthen the local validity of outcome assessment measures. We also recommend more studies that evaluate HIV outcomes alongside mental health outcomes and explore the relationship between these.

Chapter 3. Major depressive disorder and its association with adherence to antiretroviral therapy and quality of life: Cross-sectional survey of people living with HIV/AIDS in Northwest Ethiopia

Biksegn Asrat[1], Crick Lund [1,2], Fentie Ambaw[3,4], Emily Claire Garman[1], Marguerite Schneider[1]

[1]Alan J Flisher Centre for Public Mental Health, Department of Psychiatry and Mental Health, University of Cape Town

[2]Centre for Global Mental Health, King's Global Health Institute, Department of Health Services and Population Research, Institute of Psychiatry, Psychology and Neuroscience, King's College London

[3]School of Public Health, College of medicine and Health Sciences, Bahir Dar University

[4]Department of Psychiatry, College of Health Sciences, Addis Ababa University

My contribution

I conceptualised the study and led the questionnaire preparation, data collection, data entry, analysis and interpretation of results. I coordinated all the field work activities, led data entry and data cleaning. I drafted the initial and revised subsequent versions of the manuscript. The three co-authors are all involved as supervisors and provided guidance at all stages and reviewed all drafts of the manuscript. Dr Garman provided additional guidance with the analysis.

3.1. Abstract

Background: Major depression is believed to affect treatment adherence and overall QoL of PLWHA. Comorbid major depression contributes to a two-fold higher risk of mortality among PLWHA. Understanding the relationships of major depression, adherence to ART and QoL is important to identify areas for intervention. The aim of this study is to examine relationship of MDD and adherence to ART with QoL, and to investigate socio-demographic and clinical factors associated with MDD, adherence and QoL among PLWHA in Northwest Ethiopia.

Method: A cross-sectional study was conducted in the ART clinic of Felege-Hiwot Referral Hospital in Northwest Ethiopia from July to October 2019. Adult PLWHA were selected using a systematic random sampling technique. Data were collected using interview administered questionnaires and chart reviews. Mini International Neuropsychiatric Interview (MINI) and World Health Organization Quality of Life – HIV (WHOQOL-HIV) Ethiopian version instruments were used to measure MDD and QoL respectively. Adherence to ART was assessed using pill count data from patients' adherence monitoring chart. Univariate and multivariate Poisson regressions were used to assess associations of socio-demographic and clinical factors with MDD and adherence to ART. A multivariate linear regression was used to examine the associations of both MDD and adherence with overall QoL.

Result: Of the total of 393 invited participants, 391 (99.5%) completed the interviews. MDD was negatively associated with overall QoL: participants with MDD had a lower QoL score of 0.06 points compared to those with no MDD (95%CI = 0.89, 0.99; $p < 0.047$). MDD was associated with reduced adherence to ART when functional disability was controlled for (unadjusted RR=1.48; 95%CI=1.14,1.92;0.004), (adjusted RR=1.43; 95%CI:1.05, 1.96; p=0.025). However, there was no statistical association between adherence to ART and overall QoL. Functional disability was associated with both MDD (RR=5.07; 95%CI:3.27,7.86; p<0.001) and overall QoL (β=0.29; 95%CI:0.21,0.36; p<0.001).

Conclusion: The relationship between MDD and QoL indicates the need for feasible, acceptable and evidence-based mental health interventions to reduce depression and improve overall QoL of PLWHA. We recommend future studies investigate causal relationships of MDD, adherence to ART and QoL of PLWHA to better understand priority areas for intervention.

Key words: Major depressive disorder; HIV; Adherence to ART; Quality of life; Ethiopia

3.2. Introduction

Comorbid major depression affects the clinical outcomes of HIV/AIDS (78, 168) and contributes to a two-fold higher risk of mortality (169). Major depression has been one of the challenges of the 90-90-90 Joint United Nations Programme on HIV/AIDS (UNAIDS) (169) that aimed to end the epidemic of HIV/AIDS in the world . The SSA countries have been lagging far behind the target and comorbid major depression remains one of the challenges that has affected engagement with HIV care, leading to early loss to treatment and low viral suppression (169, 170).

Major depression is the most common mental disorder among PLWHA and is estimated to be two to three times higher in PLWHA than in general population (10, 169, 171). However, prevalence reports are markedly variable across studies due partially to the use of different measurement approaches. A systematic review of studies from SSA found a range of 9% to 32% prevalence of probable depression (25). A meta-analysis of studies from East Africa indicated a 38% pooled prevalence of probable depression (24). A systematic review of studies from Ethiopia reported a 37% pooled prevalence of probable depression among PLWHA (18) which was much higher compared to the 11% pooled prevalence in the general population (172).

Major depression is prevalent in PLWHA due to their vulnerability to several factors. These factors can be classified as: 1) psychosocial factors such as HIV related stigma, disability and poverty (173-175); 2) biological factors, such as structural and functional changes in the brain due to HIV infection (alteration in hypothalamic-pituitary-thyroid pathway) (48, 171, 176, 177) and due to chronic immune activation (78); and 3) other comorbid conditions, including pre-existing comorbid illnesses other than HIV/AIDS which may increase risk of depression (176).

Major depression is believed to be one of the factors that affects adherence to ART although findings are inconclusive (49, 178). While many studies support the strong association, two systematic reviews did not find an independent relationship between major depression and adherence to ART (179, 180). There are assumptions that cognitive impairment due to major depression, such as forgetfulness, poor concentration, impairment in memory, low executive functioning and difficulties with learning new behaviour, may contribute to non-adherence to ART (181). In addition, affective symptoms of major depression such as loss of interest, poor motivation, hopelessness and suicidality have also been reported to affect adherence to ART (169, 170).

Major depression is also an important determinant of QoL for PLWHA (14, 133, 170). QoL is a broad concept that includes several domains of functioning, namely physical, psychological, independence, social, environmental and spiritual functioning and can be affected by a variety of life circumstances (45, 182, 183). However, the impact of major depression on poorer QoL outcomes seems to be high for PLWHA (184).

Although the pathways are not fully understood, major depression is reported to affect overall QoL of PLWHA either directly (47-49, 185) and/or indirectly by affecting adherence to ART (50, 177). Studies in HIV populations have indicated that major depression can affect several domains of QoL directly. For example, the effect of major depression on psychological and social functioning has been reported (186, 187). There are also studies that have shown a strong association between major depression and overall QoL, but the direction of association is unclear (184, 188).

Biological studies support the association of major depression with poor physical health and poor immune functioning (177, 189, 190). For example, major depression has been reported to cause immunosuppression by altering the function of lymphocytes and decreasing natural killer cells (176). The association of major depression with decreased CD4 cells, altered immune response and increased release of proinflammatory cytokines has been commonly reported (171, 177). This may suggest that major depression can have a direct role in the physical deterioration and progress to advanced disease stage of PLWHA by interfering with immune functioning. Therefore, aiming to achieve overall improvement in QoL with the use of ART alone may not be successful without addressing major depression in PLWHA particularly in SSA (177, 191).

In Ethiopia, several studies have examined prevalence of probable depression using screening tools (18). However, diagnosis of major depression is important to develop treatment protocols, training manuals and to revise patient teaching guidelines. Furthermore, understanding relationships of major depression, adherence and QoL is important to design acceptable, feasible and evidence-based interventions for PLWHA. This study was a baseline survey used to identify and recruit cases with MDD for a group IPT intervention for PLWHA. This paper presents 1) the prevalence and associated factors of MDD; 2) the prevalence and associated factors of adherence to ART; 3) the factors associated with QoL; and 4) the associations of MDD and adherence to ART with overall QoL among PLWHA in Northwest Ethiopia.

3.3. Method

3.3.1. Setting and participants

This cross-sectional study was conducted in the ART clinic of FHRH in Northwest Ethiopia from 8th July to 7th October 2019. FHRH is one of the busiest hospitals in Northwest Ethiopia as described elsewhere (109) and serves a population of more than 7 million people. More than 3,508 PLWHA had received ART treatment at the ART clinic over the 3 months preceding the data collection period, 2948 of which were adults 18 years and above. The ART clinic is staffed by physicians, health officers, nurses, pharmacists, laboratory technologists, case managers, adherence supporters and volunteers. The ART clinic serves more than six thousand clients per year. There is a mental health service centre in the hospital which is mainly run by mental health professionals. Sample size was calculated using the Select Statistical Services computer programme using the following assumptions: i) a population proportion of 37% prevalence of depression which was taken from previous meta-analysis study findings done among PLWHA in Ethiopia (18); ii) a 5% margin of error at 95% confidence interval. The sample size was estimated to be 357. Then we have added a 10% for the non-response rate which provided a total sample size of 392.7 (approximated to 393).

Participants were recruited using a systematic sampling with a random start-point with an interval of seven. The first participant was selected randomly using a lottery method from the sample frame and the following participants were selected keeping the interval of seven. Patients medical cards were used to select every seventh client among those who were waiting for their ART follow-up at the ART clinic. Inclusion criteria were for participants to be 18 years old and above, have had at least one previous appointment at the ART, and be able to provide informed consent. Exclusion criteria were being too ill to communicate or with a major physical illness, or emotional problems as result of being in a volatile or unstable emotional state or suffering from substance induced emotional problems. In addition, those participants who diagnosed with cognitive deficits (overt dementia and delirium) by ART clinicians were excluded from the study.

3.3.2. Procedure

A research assistant approached every eligible client to explain the purpose of study, to ask for their willingness to be included in the study and to clarify the information in the informed consent sheet. Research assistants (data collectors) were nurse professionals with a BSc degree in nursing, and one with an additional MSc degree in Public Health. All of them had extensive experience in participating in research activities and data collection. They received a three-day

training on the instruments and ethical procedures by the principal investigator. Participants who signed consent forms were interviewed by trained data collectors in a private room in the ART clinic. The interviews were conducted in the local language (Amharic) and responses noted on paper questionnaires with no names and just a participant ID. The signed consent forms and completed questionnaires were kept in a locked file.

Data were collected using interview administered questionnaires and patient chart reviews. Socio-demographic, MDD, adherence to ART, QoL, functioning and social support information was collected using an interviewer administered questionnaire. HIV related clinical information such as CD4 count, duration of ART treatment and ART regimen was collected from the patient charts. Field workers, including data collectors and supervisors, were trained for three days on participant selection, informed consent administration, data collection techniques and data handling. See the questionnaire in Module one of the Appendix D.

Study participants who fulfilled the criteria for MDD or with suicidal idea were referred to group IPT counsellors for further evaluation and intervention. The counsellors evaluated the severity and treatment need of each referred study participant and they intervened based on the given standard operating procedure. Those study participants with severe mental conditions were referred to the psychiatric clinic located next to the ART clinic for advanced care and treatment.

3.3.3. Measurements

MDD: The MINI (Mini-International Neuropsychiatric Interview) depression module was used to assess MDD (192). The MINI-7.0.2 allows DSM-5 diagnosis and has been widely used as a gold standard measure of MDD (192, 193). The MINI has been adapted to the Ethiopian context for use by psychiatric nurses to detect MDD (194). The MINI adapted in Ethiopia found irritability as an important symptom of depression and “irritability” was included as an item for this study (see Appendix D, section 5). The diagnosis of MDD was made after organic causes were ruled out using the exclusion items in the MINI.

QoL: The WHOQOL-HIV Ethiopian version, that was adapted from the World Health Organization quality of life module and validated in the local language (Amharic) (195), was used to measure QoL in this study. The WHOQOL-HIV Ethiopian version was validated for use in PLWHA in Ethiopia and has been used in several studies in HIV populations (45, 184, 188). The validation shows that it has an excellent internal consistency with Cronbach alpha of 0.93. The instrument included two general items and six domains that give a total of 27 items. Study participants were asked to rate their subjective general wellbeing from 1 to 5 where low scores indicate low general

wellbeing as perceived by study participants. Mean QoL score was calculated by dividing the sum scores of QoL by 27. Mean scores of each domain of QoL (physical, psychological, independence, social, environmental and spiritual) were also calculated independently.

Adherence to ART: We assessed adherence to ART using the pill count data, captured from patients' re-fill chart and used for the purpose of clinical monitoring, together with clinicians' report of skipped doses. Pill count is a valid method used to measure adherence to ART and has been used by several studies in resource limited settings (196, 197). Upon examination of the frequencies and distribution of our data, we found that the data were skewed towards high adherence. Therefore, we narrowly defined *high adherence* as taking all doses of ART medications as prescribed by the clinician since the last appointment and *suboptimal adherence* was defined as skipping one or more doses of the prescribed medications.

Functional disability: The World Health Organization Disability Assessment Schedule (WHODAS-12) was used to measure functional disability. The WHODAS-12 instrument was high in acceptability, understandability and relevance to the WHODAS-36 instrument for the Ethiopian context (198). Each item of the WHODAS-12 has Likert scale response options (No Difficulty = 0, Mild Difficulty = 1, Moderate Difficulty = 2, Severe Difficulty = 3, Extreme Difficulty/'Cannot Do' = 4). The scores of each item were summed and total scores can range from minimum of 0 to maximum of 48. In this study, functional disability was defined as a score of 36 or higher (i.e. having severe or extreme difficulty). The use of simple scoring method (adding up scores) has been a recommended approach by the WHO.

Perceived social support (PSS): The Multidimensional Scale of Perceived Social Support (MSPSS) was used to evaluate perceived social support. The MSPSS has been adapted and validated in different settings across the world including in Africa (199-201). The instrument has been shown to be reliable and valid for use in African cultures, for instance in Malawi (202) and Uganda (203). The instrument evaluates perceived social support adequacy using three subscales: family, friends and significant others (200). The MSPSS has 12-items (each subscale has 4-items) with 7-point Likert scale response options from 1 (very strongly disagree) to 7 (very strongly agree) (200). The value of each item was summed, and mean scores were calculated. The mean scores can range from minimum of 1 to maximum of 7. In this study mean scores ranging from 1 to 3 indicate low PSS, from 3 to 5 indicate moderate PSS and 5 to 7 indicate high PSS (204).

3.3.4. Data analysis

Data were entered into Epidata and analysed using SPSS statistics version 26 computer programme. Items of MDD, QoL, adherence to ART, PSS, functional disability and suicidality were computed to generate aggregated variables. Descriptive statistical analysis was used to summarise outcome variables, socio-demographic and clinical factors.

Univariate Poisson regression was used to identify association of each socio-demographic and clinical factor with MDD, and risk ratios are reported (205). Poisson regression can be used for binary data to calculate risk ratios (205). In multivariate Poisson regression, all factors with p-value <0.2 in the univariate Poisson regression were entered in a multivariate analysis to control for confounding factors and generate adjusted risk ratios. Similarly, we used univariate Poisson regression to identify the association of socio-demographic and clinical variables with adherence to ART, and risk ratios are reported. All factors with p-value of <0.2 in the univariate Poisson regression were entered in a multivariate analysis to control for confounding factors and generate adjusted risk ratios.

We used linear regression to identify factors associated with the overall QoL. First, each of the socio-demographic and clinical variables were entered in a univariate model. Then, factors associated with overall QoL in the univariate analyses at a p-value <0.2 were entered in a multivariate linear regression to adjust for confounding factors. These factors were also entered in a multivariate linear regression, for each domain of QoL separately, to examine the association of socio-demographic and clinical factors with each domain of QoL. Finally, association of MDD and adherence to ART with overall QoL was examined using a generalised linear model. All socio-demographic and clinical factors associated with overall QoL at p-value of <0.05 in the previous analysis were adjusted for in the model. An interaction analysis was also used in the model to assess interaction of MDD and adherence to ART on overall QoL.

3.3.5. Ethics Approval and Consent to Participate

This study was approved by the University of Cape Town's Human Research Ethics Committee (HREC reference No. 653/2018). In addition, an approval letter was obtained from Bahir Dar University College of Medicine and Health Sciences' Ethics Committee (reference No. 007/2018) and a permission letter was obtained from the Amhara Public Health Institute (APHI). All study participants signed a written informed consent. Illiterate study participants signed by fingerprint after a witness read the written informed consent. See the ethical approval letters in the Appendices A and B and the consent form Appendix E.

3.4. Results

3.4.1. Socio-demographic and clinical characteristics of study participants

Of the total of 393 invited participants, 391 (99.5%) completed the interviews. More than two-thirds (69.3%, n=269) of the study participants were women. The mean age of participants was 38.7 years old (SD=9.1) ranging from 18 to 78 years old respectively. Three quarters (74.6%, n=288) of the study participants were on first line ART treatments.

Table 5. Socio-demographic and clinical characteristics of the study participants, Felege-Hiwot Referral Hospital (FHRH), Northwest Ethiopia (N=391).

Socio-demographic and clinical characteristics		Frequency	Percent
Age in years	18-29	51	13.2
	30-39	161	41.8
	40-49	119	30.9
	50+	54	14.0
Gender	Male	119	30.7
	Female	269	69.3
Marital status	Single	53	13.6
	Married/in relationship	187	47.8
	Divorced/widowed	151	38.6
Educational status	Illiterate	123	31.5
	Primary education	125	32.0
	Secondary education	93	23.8
	Tertiary education	50	12.8
Employment	Public servant	84	21.5
	Self employed	182	46.7
	None employed	124	31.8
Current CD4 count (last 6 months)	<200	28	7.6
	200-349	69	18.6
	350-499	95	25.7
	>500	178	48.1
Antiretroviral therapy regimen	First-line	288	74.6
	Second-line	98	25.4
Duration of ART treatment in years	1 – 5	72	19.0
	6 – 10	134	35.4
	11 and above	175	45.6
Major depressive disorder	Yes	127	32.5
	No	264	67.5
ART adherence	High adherence	289	81.9
	Suboptimal adherence	64	18.1

NOTE: First-line regimen is the use of first choice antiviral drugs and a switch to second-line regimen is recommended when there is treatment failure with first-line treatments.

3.4.2. Prevalence and associated factors of MDD

The overall prevalence of MDD was 32.5% (n=127; 95%CI: 28.1,37.3) and it was 46.3% (n=57) among illiterate, 44.4% (n=55) among unemployed, 65.4% (n=100) among functionally disabled study participants. The prevalence of MDD in each variable is presented in Table 5.

In the univariate regression (unadjusted analysis), being divorced or widowed, illiterate, unemployed, with low PSS, and on second line ART regimen were significantly associated with MDD. Results from the multivariate Poisson regression (adjusted analysis) show that only functional disability was associated with MDD: those who had functional disability (65.4%, n=100) had 5.07 times the risk of MDD compared to those who had no functional disability (11%, n=26) (95%CI: 3.27,7.86; p<0.001). See Table 6.

3.4.3. Prevalence of adherence to ART and associated factors

Overall, 81.9% of respondents (n=289; 95%CI: 77.9, 85.8) had high adherence to ART (see Table 5). MDD was associated with reduced adherence to ART when functional disability was controlled for: those who had MDD (62.2%, n=74) had 1.43 times the risk of suboptimal adherence to ART compared to those who had no MDD (91.9%, n=215; 95%CI: 1.05,1.96; p=0.025). See Table 7.

Table 6. Poisson regression: Prevalence of and factors associated with major depressive disorder among people living with HIV/AIDS in Felege-Hiwot Referral Hospital, Northwest Ethiopia (N=391).

Socio-demographic and clinical factors		Prevalence of MDD, % (n)	Unadjusted Poisson regression			Adjusted Poisson regression		
			Risk ratio	95%CI	P value	Risk ratio	95%CI	P value
Age in years [a]	18-29	31.4 (16)	1.11	0.56, 2.19	0.770			
	30-39	33.5 (54)	1.18	0.69, 2.04	0.544			
	40-49	33.6 (40)	1.19	0.67, 2.09	0.555			
	50+	29.6 (16)	Reference	Reference				
Gender	Male	25.2 (30)	Reference	Reference				
	Female	36.1 (97)	1.47	0.97, 2.21	0.067	1.13	0.72, 1.78	0.600
Marital status	Married/in relationship	25.7 (48)	Reference	Reference		Reference	Reference	
	Single	37.7 (20)	1.47	0.87, 2.48	0.148	1.13	0.65, 1.96	0.675
	Divorced/widowed	39.1 (59)	1.52	1.04, 2.23	0.031	1.01	0.67, 1.53	0.968
Educational status	Illiterate	46.3 (57)	2.11	1.11, 4.02	0.024	1.04	0.43, 2.50	0.930
	Primary education	28.0 (35)	1.27	0.65, 2.51	0.485	0.90	0.39, 2.10	0.812
	Secondary education	25.8 (24)	1.17	0.58, 2.40	0.661	0.83	0.35, 1.99	0.682
	Tertiary education	22.0 (11)	Reference	Reference		Reference		
Employment	Public employed	17.9 (15)	Reference	Reference		Reference		
	Self employed	30.8 (56)	1.64	0.94, 2.85	0.083	1.40	0.68, 2.89	0.366
	Unemployed	44.4 (55)	2.36	1.35, 4.11	<0.003	1.75	0.84, 3.63	0.135
Perceived social support	High support	24.3 (55)	Reference	Reference		Reference	Reference	
	Moderate support	41.9 (54)	1.70	1.17, 2.46	<0.005	1.21	0.82, 1.78	0.337
	Low support	55.6 (15)	2.25	1.28, 3.97	<0.005	1.25	0.67, 2.31	0.481
ART regimen	First-line	27.8 (80)	Reference	Reference		Reference	Reference	
	Second-line	45.9 (45)	1.64	1.14, 2.36	<0.008	1.31	0.90, 1.91	0.157
Functional disability	No	11.0 (26)	Reference	Reference		Reference	Reference	
	Yes	65.4 (100)	5.76	3.77, 8.81	<0.001	**5.07**	**3.27, 7.86**	**<0.001**
Current CD4 count (last 6 months) [a]	<200	35.7 (10)	0.98	0.51, 1.91	0.969			
	200-349	26.1 (18)	0.72	0.43, 1.21	0.215			
	350-499	28.4 (27)	0.78	0.51, 1.22	0.285			
	>500	36.5 (65)	Reference	Reference				
ART treatment duration in years [a]	1 – 5	29.2 (21)	0.81	0.49, 1.32	0.387			
	6 – 10	29.1 (39)	0.80	0.54, 1.19	0.278			
	11 and above	36.4 (63)	Reference	Reference				

NOTE: First-line regimen is the use of first choice antiviral drugs and a switch to second-line regimen is recommended when there is treatment failure with first-line treatments. ART: antiretroviral therapy. [a] variables not included in multivariate Poisson regression; * statistically associated with MDD.

Table 7. Poisson regression: Prevalence of and factors associated with adherence to antiretroviral therapy among people living with HIV/AIDS in Felege-Hiwot Referral Hospital, Northwest Ethiopia (N=353).

Socio-demographic and clinical factors		Prevalence of high adherence, % (n)	Unadjusted Poisson regression			Adjusted Poisson regression		
			Risk ratio	95%CI	P value	Risk ratio	95%CI	P value
Age in years [a]	18-29	79.2 (38)	Reference					
	30-39	82.4 (122)	1.04	0.73, 1.47	0.845			
	40-49	81.1 (86)	1.02	0.71, 1.47	0.920			
	50+	84.4 (38)	1.06	0.69, 1.64	0.792			
Gender [a]	Male	83.3 (90)	1.03	0.80, 1.32	0.840			
	Female	81.0 (196)	Reference					
Marital status [a]	Single	76.0 (38)	Reference					
	Married/ in relationship	85.7 (144)	1.13	0.79, 1.61	0.510			
	Divorced/widowed	79.3 (107)	1.04	0.72, 1.51	0.824			
Educational status [a]	Illiterate	77.9 (88)	Reference					
	Primary education	79.5 (89)	1.02	0.76, 1.37	0.893			
	Secondary education	85.4 (70)	1.09	0.80, 1.50	0.566			
	Tertiary education	91.3 (42)	1.17	0.81, 1.69	0.396			
Employment [a]	Public employed	91.9 (68)	1.21	0.88, 1.66	0.245			
	Self employed	81.3 (135)	1.07	0.82, 1.40	0.631			
	Unemployed	75.9 (85)	Reference					
Perceived social support [a]	High support	82.8 (164)	1.14	0.74, 1.75	0.552			
	Moderate support	82.8 (101)	1.14	0.73, 1.78	0.568			
	Low support	69.2 (18)	Reference					
ART regimen [a]	First-line	84.4 (217)	1.13	0.86, 1.47	0.383			
	Second-line	75.8 (69)	Reference					
Functional disability	No	89.6 (189)	1.27	0.99, 1.62	0.052	1.06	0.79, 1.41	0.710
	Yes	70.8 (98)	Reference			Reference		
Current CD4 count (last 6 months) [a]	<200	79.2 (19)	Reference					
	200-349	81.3 (52)	1.08	0.70, 1.68	0.719			
	350-499	86.0 (74)	1.15	0.76, 1.73	0.512			
	>500	81.8 (130)	1.09	0.74, 1.60	0.658			
ART treatment duration in years [a]	1 – 5	82.3 (51)	Reference					
	6 – 10	82.4 (98)	1.05	0.76, 1.45	0.765			
	11 and above	83.1 (133)	1.06	0.78, 1.44	0.709			
Major depressive disorder	No	91.9 (215)	1.48	1.14, 1.92	0.004	1.43	1.05, 1.96	0.025
	Yes	62.2 (74)	Reference			Reference		

[a] variables not included in multivariate Poisson regression; * statistically associated with MDD; ART: antiretroviral therapy

3.4.4. Factors associated with QoL

The overall QoL mean score was 3.86 (SD=0.42) and the mean scores for physical, psychological, independence, social, environmental and spiritual domains were 4.16 (SD=0.56), 3.73 (SD=0.65), 4.02 (SD=0.56), 3.76 (SD=0.60), 3.27 (SD=0.61) and 4.42 (0.44) respectively. The data of QoL was normally distributed and all assumptions were met to conduct linear regression. The multivariate linear regression shows that a higher level of education was positively associated with overall QoL: those with tertiary education had a higher QoL score of 0.34 compared to those who were illiterate (95%CI: 0.19,0.49; p<0.001) (See Table 8). Taking first-line ART treatment was positively associated with overall QoL: participants who were taking first-line ART treatment had a higher QoL score of 0.12 compared to participants who were taking second-line ART treatment (95%CI: 0.03,0.20; p<0.008). Similarly, taking ART for a longer duration was also positively associated with overall QoL: those who had taken ART for 6-10 years had a higher QoL score of 0.12 compared to those who had taken ART for less than 6 years (95%CI: 0.02,0.22; p=0.022). High PSS was positively associated with overall QoL: participants who had high PSS had a higher QoL score of 0.43 compared to those who had low PSS (95%CI: 0.29,0.57; p<0.001). Functional disability was also associated with overall QoL: those who had no functional disability had a higher QoL score of 0.29 compared to those who had functional disability (95%CI: 0.21,0.36; p<0.001).

In addition, the adjusted linear regressions by domains of QoL show that age and employment were statistically associated with one or more domains of QoL. In the univariate analysis, being married or in a relationship and public employment were significantly associated with a higher QoL score. See Table 9.

Table 8. Linear regression: Association of socio-demographic and clinical factors with overall quality of life among people living with HIV/AIDS in Felege-Hiwot Referral Hospital, Northwest Ethiopia (N=391).

Factors		Mean (SD)	Unadjusted linear regression			Adjusted multivariate linear regression		
			Coefficient	95%CI	P value	Coefficient	95%CI	P value
Age in years	18-29	3.76 (0.40)	Reference	Reference		Reference	Reference	
	30-39	3.86 (0.44)	0.27	-0.26, 0.80	0.313	0.07	-0.04, 0.19	0.209
	40-49	3.91 (0.43)	0.49	-0.07, 1.05	0.087	0.10	-0.2, 0.23	0.102
	50+	3.83 (0.37)	0.18	-0.48, 0.83	0.601	0.06	-0.08.0.21	0.371
Gender [a]	Male	3.90 (0.39)	0.23	-0.16, 0.61	0.255			
	Female	3.84 (0.44)	Reference	Reference				
Marital status	Single	3.77 (0.45)	-0.08	-0.65, 0.48	0.770	-0.04	-0.16, 0.08	0.530
	Married/ in relationship	3.93 (0.39)	0.57	0.18, 0.95	<0.004	-0.01	-0.08, 0.08	0.974
	Divorced/widowed	3.79 (0.45)	Reference	Reference		Reference	Reference	
Educational	Illiterate	3.67 (0.50)	Reference	Reference		Reference	Reference	
status	Primary education	3.87 (0.37)	0.78	0.35, 1.21	<0.001	**0.13**	**0.03, 0.22**	**<0.008**
	Secondary education	3.95 (0.35)	1.12	0.65, 1.58	<0.001	**0.20**	**0.09, 0.31**	**<0.001**
	Tertiary education	4.09 (0.31)	1.69	1.13, 2.25	<0.001	**0.34**	**0.19, 0.49**	**<0.001**
Employment	Public employed	4.01 (0.32)	0.85	0.37, 1.33	0.001	-0.07	-0.19, 0.05	0.274
status	Self employed	3.83 (0.42)	0.14	-0.27, 0.55	0.499	0.01	-0.08, 0.09	0.886
	None employed	3.81 (0.44)	Reference	Reference		Reference	Reference	
ART regimen	First-line	3.90 (0.41)	0.59	0.18, 0.99	<0.005	**0.12**	**0.03, 0.20**	**<0.008**
	Second-line	3.76 (0.45)	Reference	Reference		Reference	Reference	
Current CD4	<200	3.85 (0.45)	Reference	Reference		Reference	Reference	
count (last 6	200-349	3.88 (0.37)	0.34	-0.315, 0.99	0.307	-0.01	-0.14, 0.13	0.937
months)	350-499	3.94 (0.38)	0.58	-0.042, 1.20	0.067	0.06	-0.07, 0.19	0.343
	>500	3.83 (0.43)	0.16	-0.40, 0.72	0.575	0.01	-0.11, 0.13	0.865
Duration of ART	1 – 5	3.83 (0.49)	Reference			Reference	Reference	
treatment in	6 – 10	3.91 (0.41)	0.35	-0.14, 0.85	0.157	**0.12**	**0.02, 0.22**	**0.022**
years	11 and above	3.84 (0.41)	0.05	-0.42, 0.52	0.835	-0.01	-0.11, 0.10	0.931
Perceived social	Low support	3.38 (0.62)	Reference	Reference		Reference	Reference	
support	Moderate support	3.68 (0.36)	0.90	0.27, 1.54	0.006	**0.18**	**0.04, 0.33**	**0.014**
	High support	3.86 (0.42)	2.19	1.59, 2.80	<0.001	**0.43**	**0.29, 0.57**	**<0.001**
Functional	No	4.01 (0.33)	1.42	1.08, 1.75	<0.001	**0.29**	**0.21, 0.36**	**<0.001**
disability	Yes	3.64 (0.47)	Reference	Reference		Reference	Reference	

NOTE: First-line regimen is the use of first choice antiviral drugs and a switch to second-line regimen is recommended when there is treatment failure with first-line treatments. [a] not included in the final model of analysis; ART – antiretroviral therapy.

Table 9. Linear regression: Association of socio-demographic and clinical factors with the domains of quality of life among people living with HIV/AIDS in Felege-Hiwot Referral Hospital, Northwest Ethiopia (N=391).

Socio-demographic and clinical factors		Physical β (95%CI)	Psychological β (95%CI)	Independence β (95%CI)	Social β (95%CI)	Environmental β (95%CI)	Spiritual β (95%CI)
Age	18-29	Reference	Reference	Reference	Reference	Reference	Reference
	30-39	-0.05 (-0.22, 0.11)	0.07 (-0.09, 0.23)	-0.01 (-0.16, 0.15)	0.12 (-0.03, 0.28)	**0.18 (0.01, 0.37)**	0.07 (-0.07, 0.20)
	40-49	-0.10 (-0.27, 0.08)	0.10 (-0.07, 0.27)	-0.03 (-0.20, 0.14)	0.10 (0.07, 0.27)	**0.26 (0.06, 0.46)**	0.08 (-0.06, 0.23)
	50+	-0.11 (-0.32, 0.09)	0.16 (-0.05, 0.36)	-0.09 (-0.30, 0.09)	0.14 (-0.05, 0.33)	**0.23 (0.02, 0.46)**	0.11 (-0.05, 0.28)
Marital status	Married/relationship	Reference	Reference	Reference	Reference	Reference	Reference
	Single	-0.10 (-0.27, 0.07)	0.01 (-0.16, 0.17)	-0.09 (-0.25, 0.07)	-0.16 (-0.32, 0.01)	0.18 (-0.02, 0.37)	-0.09 (-0.23, 0.05)
	Divorced/ widowed	0.01 (-0.10, 0.13)	0.07 (-0.04, 0.18)	0.06 (-0.05, 0.17)	-0.08 (-0.19, 0.03)	0.07 (-0.07, 0.20)	-0.05 (-0.14, 0.05)
Educational status	Illiterate	Reference	Reference	Reference	Reference	Reference	Reference
	Primary education	**0.20 (0.07, 0.33)**	**0.17 (0.04, 0.30)**	**0.22 (0.09, 0.35)**	0.11 (-0.01, 0.24)	0.12 (-0.03, 0.28)	**0.12 (0.01, 0.22)**
	Secondary education	**0.21 (0.06, 0.35)**	**0.22 (0.07, 0.36)**	**0.21 (0.07, 0.35)**	0.13 (-0.01, 0.27)	**0.31 (0.14, 0.48)**	**0.13 (0.01, 0.25)**
	Tertiary education	**0.27 (0.06, 0.48)**	**0.51 (0.30, 0.72)**	**0.35 (0.15, 0.56)**	0.16 (-0.04, 0.37)	**0.33 (0.10, 0.57)**	**0.23 (0.06, 0.41)**
Employment status	Public servant	-0.08 (-0.26, 0.09)	-0.09 (-0.26, 0.09)	0.01 (-0.16, 0.18)	-0.01 (-0.17, 0.16)	-0.04 (-0.23, 0.16)	-0.09 (-0.23, 0.06)
	Self employed	-0.04 (-0.16, 0.08)	**0.17 (0.05, 0.29)**	0.07 (-0.04, 0.19)	-0.11 (-0.22, 0.01)	-0.01 (-0.14, 0.13)	-0.07 (-0.17, 0.02)
	Unemployed	Reference	Reference	Reference	Reference	Reference	Reference
Perceived social support	Low support	Reference	Reference	Reference	Reference	Reference	Reference
	Moderate support	0.15 (-0.05, 0.34)	**0.34 (0.15, 0.53)**	**0.23 (0.05, 0.42)**	0.10 (-0.08, 0.29)	0.11 (-0.13, 0.34)	**0.19 (0.03, 0.35)**
	High support	**0.25 (0.06, 0.44)**	**0.60 (0.42, 0.79)**	**0.37 (0.19, 0.56)**	**0.68 (0.50, 0.87)**	**0.45 (0.22, 0.68)**	**0.28 (0.13, 0.44)**
ART regimen	First-line	**0.15 (0.04, 0.27)**	**0.19 (0.07, 0.30)**	**0.11 (0.01, 0.23)**	0.10 (-0.01, 0.21)	0.08 (-0.05, 0.22)	0.08 (-0.02, 0.17)
	Second-line	Reference	Reference	Reference	Reference	Reference	Reference
Functional Disability	No	**0.39 (0.28, 0.49)**	**0.55 (0.44, 0.66)**	**0.35 (0.25, 0.45)**	**0.25 (0.15, 0.35)**	0.10 (-0.02, 0.22)	**0.17 (0.08, 0.26)**
	Yes	Reference	Reference	Reference	Reference	Reference	Reference
Current CD4 count (last 6 months)	<200	Reference	Reference	Reference	Reference	Reference	Reference
	200-349	-0.07 (-0.27, 0.12)	0.07 (-0.12, 0.26)	-0.03 (-0.21, 0.16)	0.04 (-0.14, 0.22)	-0.08 (-0.30, 0.15)	0.14 (-0.02, 0.30)
	350-499	0.03 (-0.16, 0.21)	0.08 (-0.10, 0.26)	0.07 (-0.10, 0.25)	0.04 (-0.14, 0.21)	-0.03 (-0.24, 0.18)	0.13 (-0.02, 0.28)
	>500	0.01 (-0.17, 0.17)	0.01 (-0.15, 0.18)	-0.04 (-0.20, 0.12)	0.03 (-0.13, 0.19)	-0.05 (-0.24, 0.15)	0.05 (-0.09, 0.19)
ART treatment duration in years	1 – 5	Reference	Reference	Reference	Reference	Reference	Reference
	6 – 10	**0.17 (0.03, 0.32)**	0.12 (-0.02, 0.27)	0.13 (-0.01, 0.27)	0.05 (-0.09, 0.19)	0.01 (-0.15, 0.18)	**0.17 (0.05, 0.29)**
	11+	0.03 (-0.11, 0.18)	0.03 (-0.12, 0.17)	-0.05 (-0.19, 0.09)	-0.04 (-0.09, 0.19)	-0.14 (-0.30, 0.03)	0.04 (-0.08, 0.16)

The results in this table were identified in multivariate linear regression. All variables associated with overall QoL at >0.2 were controlled multivariate analyses with each domain of QoL. First-line regimen is the use of first choice antiviral drugs and a switch to second-line regimen is recommended when there is treatment failure with first-line treatments. ART: antiretroviral therapy

3.4.5. Association of MDD and adherence to ART with overall QOL

After controlling for socio-demographic and clinical factors associated with overall QoL, results of the multivariate linear regression show that MDD was negatively associated with overall QoL: participants with MDD had a lower QoL score of 0.06 compared to those with no MDD (95%CI: 0.89,0.99; p<0.047) (see Table 6). However, there was no statistical association between adherence to ART and overall QOL. The generalised linear model presented no interaction effect of MDD and adherence to ART on QoL scores (95%CI: 0.94,1.07; β=0.01; p=0.866). See Table 10.

Table 10. Generalised linear model univariate analysis: Association of major depressive disorder and adherence to antiretroviral therapy with the overall quality of life after adjusting for socio-demographic and clinical factors (N=391).

Covariates		Mean (SD)	Adjusted linear regression		
			Coefficient	95%CI	P value
Major depressive disorder	No	3.99 (0.33)	Reference	**Reference**	
	Yes	3.59 (0.47)	**-0.06**	**0.89, 0.99**	**0.047**
Adherence to ART	High adherence	3.86 (0.40)	Reference		
	Suboptimal adherence	3.73 (0.46)	-0.03	0.93, 1.02	0.277
MDD*Adherence to ART			0.01	0.94, 1.07	0.866

NOTE: All variables associated with overall QoL at >0.05 were controlled for in this model (age, marital status, educational status, employment status, antiretroviral therapy (ART) regimen, CD4 count, duration of ART treatment, perceived social support and functional disability). ART: antiretroviral therapy.

3.5. Discussion

Unlike most of the previous studies in HIV populations in Ethiopia, this study examined the prevalence of major depression using a diagnostic instrument. We found that one third of the study participants had MDD, and that being divorced or widowed, illiterate, unemployed, with low perceived social support, and on second line ART regimen were significantly associated with MDD in univariate regressions (unadjusted analysis). MDD was strongly associated with functional disability and suboptimal adherence to ART in the multivariate regression (adjusted analysis). We also identified associations between higher overall QoL and better educational status, better PSS, functioning, taking ART for a longer duration and taking first-line ART treatments.

More than two thirds of the study participants were women. However, there was no difference in prevalence of MDD between men and women. The reason for the majority of the participants being women could be due to a higher prevalence of HIV/AIDS among women than men. This is supported by several reports that have shown that HIV/AIDS is more prevalent in women than

men in Ethiopia (206). Our study found that there was no difference in prevalence of MDD by age and gender which is in agreement with findings from another study reporting that MDD is prevalent in all age groups and in both genders of PLWHA (207). However, there are also contrasting findings from other studies in the general population. *Gender and income level have associations with depression, for example* depression was found to be more prevalent in females than males (208). Biological impact of HIV (209), stigma, poor social support, and low socio-economic conditions (207) all contribute to a high prevalence of MDD among PLWHA.

In this study, there was a significant association between PSS and MDD in the univariate regression but no association between PSS and MDD in the multivariate regression. This may be due to, 1) introduction of several confounding variables in the multivariable model, 2) PLWHA may perceive the extent of social support differently as stigma predominates, and 3) It may also be due to less validity of the measure for HIV population in Ethiopian context. This finding is inconsistent with a systematic review of longitudinal studies that reported poorer PSS causes worse outcomes of MDD in terms of functioning and recovery (210) and with another systematic review of studies from Africa that reported presence of a strong relationship between PSS and MDD (211). However, a systematic review of studies from high-income countries (212) and another longitudinal study among adolescents from China (213) reported no relationship between level of PSS and MDD. There is conflicting global evidence on a causal relationship between PSS and MDD. Interpersonal theories of depression indicate that poor social support leads to onset of MDD (35). In contrast, a more recent longitudinal study presented evidence that PSS is a consequence of MDD contrary to social causation theories of depression (213), reporting that the negative views of people with MDD can make it uncomfortable for peers to provide social support. In addition, lack of social skills of people with MDD to create and maintain a relationship may result in a social avoidance state. Despite our findings, we believe that social support could be an important intervention for MDD. MDD caused by a psychosocial crisis can be effectively treated by strong social support, which helps to decrease interpersonal stress and improve interpersonal skills (35).

Our study shows that functional disability was independently associated with MDD. Functional disability prevents people with MDD from performing daily activities, leads to loss of social roles and lack of access to resources for basic needs (214). Failure to fulfil self needs and social responsibilities can lead to onset of full blown MDD, or reciprocally MDD can lead to functional disability (215). Furthermore, people with functional disability need more intensive social and material support due to poverty and this could aggravate pre-existing MDD (31).

Our finding about the association of several socio-demographic and clinical factors with overall QoL is consistent with previous findings. Better educational status (216-218), being employed (219), good social support (49, 216), functioning (49) and access to first line ART treatment (218, 220) have been identified as predictors of improved QoL. Our findings support the hypothesis that PLWHA with better education and with good physical functioning could have better income and employment opportunities to gain better QoL.

None of the socio-demographic and clinical factors showed statistical associations with adherence to ART which is inconsistent with previous findings (180). This can be explained by challenges in measuring adherence to ART using pill count There was also inconsistency in using specific measures across studies that may be misleading in assessing treatment adherence in HIV populations. But MDD seems an important predictor of suboptimal adherence to ART which is supported by several findings from previous studies (75, 76). This could be due to MDD related cognitive impairment, such as memory loss and forgetfulness in taking ART medications (77-79), or due to poor motivation, hopelessness and wishing to die (4). Our findings show the need to integrate mental health interventions with existing HIV care as MDD has been found to be one of the major barriers to the global agenda to end the HIV epidemic specially in SSA countries (169, 170).

The observed relationship between MDD and overall QoL was consistent with previous findings in HIV populations (216, 218, 219). Evidence shows that MDD consistently leads to worse health outcomes in PLHWA not solely due to difference in adherence to ART but may also be due to direct effect of MDD on physiological functioning (168). Firstly, MDD can affect QoL by interfering with immune system functioning. Secondly, MDD affects positive thoughts for change that can lead to lower adherence to ART. Thirdly, the relationship between MDD and poor QoL can also explained by indirect effects of MDD on QoL such as financial insecurity, unemployment and financial dependency on others (211). The overall findings of this study indicated that addressing MDD should be a priority to facilitate recovery and functioning of PLWHA. A recent systematic review and meta-analysis of RCTs found that psychological treatments enhance immune system functioning (221). Therefore, we recommend the use of psychological treatments for treatment of depressive symptoms and to improve immune functioning that could help to improve overall QoL of PLWHA. We recommend that mental health researchers develop evidence-based psychological treatments that are appropriate for PLWHA to manage depression, and to improve adherence to ART and overall quality of life of PLWHA. Furthermore, we believe that this study could have several implications for health care providers and policy makers to consider mental

health conditions as a priority and to act accordingly. Specifically, routine screening services for depression and other mental disorders should be established at ART clinics and mental health services integrated with HIV care services in Ethiopia.

A major strength of this study was the use of instruments validated in Ethiopia. However, it has also several limitations. Firstly, it is a cross-sectional study that doesn't allow us to identify causal relationships between independent and outcome variables. Secondly, the use of pill count data alone to measure adherence to ART may not be the right approach and future studies should consider alternative approaches. Thirdly, readers should note that *suboptimal adherence to ART* was defined narrowly as skipping one or more doses of ART medications. Fourth, there may have been recall bias in the manner in which study participants shared their information. Fifth, there was no measure of socio-economic status, which means that the association between MDD and quality of life could have been confounded by socioeconomic factors. Sixth, the use of nurse-administered fully structured diagnostic measure (MINI) to diagnose MDD may also be a limitation as such an administration of the MINI is not a gold standard measure for diagnosis. Seventh, MDD could have had a mediating effect on the relationship between non-adherence and QoL. However, this did not seem to be supported by statistical analysis.

3.6. Conclusion

This study indicates that both MDD and QoL have a strong relationship with functional disability among PLWHA in Northwest Ethiopia. The strong relationship between MDD and QoL indicates the need to integrate feasible, acceptable and evidence-based mental health interventions within the existing HIV care services to improve the overall QoL of PLWHA. We recommend future studies to investigate causal relationships of MDD, adherence to ART and QoL of PLWHA to better understand priority areas for intervention.

Chapter 4. Adaptation of the WHO group interpersonal therapy for people living with HIV/AIDS in Northwest Ethiopia: a qualitative study

Biksegn Asrat[1], Crick Lund [1,2], Fentie Ambaw[3,4], Marguerite Schneider[1]

[1]Alan J Flisher Centre for Public Mental Health, Department of Psychiatry and Mental Health, University of Cape Town

[2]Centre for Global Mental Health, King's Global Health Institute, Department of Health Services and Population Research, Institute of Psychiatry, Psychology and Neuroscience, King's College London

[3]School of Public Health, Medicine and College of Health Sciences, Bahir Dar University

[4]Department of Psychiatry, College of Health Sciences, Addis Ababa University

My contribution

I conceptualised the study and led the data acquisition, data entry, analysis and interpretation of results. I coordinated all the field work activities, led data entry and data cleaning. I drafted the initial and revised subsequent versions of the manuscript. The three co-authors are all involved as supervisors and provided guidance at all stages and reviewed all drafts of the manuscript.

4.1. Abstract

Background: Psychological treatments improve depressive symptoms in PLWHA. Adaptation of treatments should be based on explanatory models of depression and other elements within the given context. This study aimed to examine explanatory models of depression and acceptable approaches for implementation of group IPT in Northwest Ethiopia.

Methods: Qualitative data were collected from April to May 2019 from a total of 18 participants using focus group discussions. Three separate focus group discussions were conducted among case managers (6 participants), adherence supporters (5 participants) and service users (7 participants). Data were analysed using the framework approach.

Results: PLWHA attributed depression to psychosocial problems, spiritual factors and biological factors. Depression had several impacts at individual and family level. Group-based IPT was acceptable if provided by trained peer counsellors.

Conclusion: The current study findings informed how to conduct feasibility and acceptability trials of group IPT in the HIV population in Ethiopia.

Key words: Adaptation; Explanatory models; Group Interpersonal Therapy; HIV/AIDS; World Health Organization

4.2. Introduction

A number of psychological treatments show benefits for improving depressive symptoms among different groups of people (222, 223). However, when they are implemented in different settings, they may not appear as effective as they were during their development (223-226). This indicates the need for dynamic adaptation and contextualisation of psychological treatments when they are replicated in different settings (223, 225). The use of Western treatment models in diversified settings using an etic approach can invalidate psychological treatments (227). Chowdhary and colleagues support this argument in a systematic review showing that trials following proper adaptation and contextualisation of psychological treatments were more effective than trials that used non-adapted treatments (104). The adaptation of evidence-based psychological treatments requires appropriate understanding of local explanatory models and contextualisation of preferred treatments into the existing health care systems (89, 104, 227). Although several studies have shown the effectiveness of psychological treatments for depression in LMICs, the attention given to appropriate adaptation remains limited (89).

Studies have shown that group IPT has been effective for treatment of depression in LMICs (90, 137, 228). However, there is a challenge to integrating group IPT into the routine health care systems because of a lack of systematic adaptation and contextualisation of the therapy (89). There are several issues that should be considered while adapting group IPT for treatment of depression in LMICs (229). Furthermore, engaging stakeholders in the process of contextualisation of the group IPT is fundamental to enhance its acceptability and effectiveness (89, 227, 229). In relation to PLWHA, there are several positive results on the effectiveness of group IPT for treatment of depression in LMICs (228-231). However, systematic adaptation of group IPT specifically for PLWHA has received minimal attention to expand the intervention to larger populations.

The Kleinman's explanatory model of illness remains a useful approach to integrate cultural beliefs within clinical processes by exploring views of therapists and patients on the nature, name, cause, course and desired treatment for a specific episode of illness (112, 232, 233). This model views cultural and psychosocial variables as important determinants of health (234), and it helps to understand and integrate stakeholders views within health care systems (232).

Symptoms of depression and HIV/AIDS are intertwined with each other (227, 235). For instance, several narratives indicate that PLWHA consider depressive symptoms as part of HIV/AIDS (227, 231, 235) and they believe that depression is caused by HIV/AIDS (231, 235). Moreover, many

others attribute depression to spiritual possession and witchcraft (227, 231). Similarly, PLWHA may have different beliefs on the impacts of depression and treatment needs including on the preferred approach of interventions and delivering agents for the intervention.

Evidence shows that depression is caused by biological, psychological or/and social vulnerabilities (22, 29, 236). The biological process of HIV such as “cytokine-induced sickness behavior” and immune activation markers can cause onset of depressive features in PLWHA (48, 237, 238). Furthermore, the life threatening nature of HIV/AIDS has a psychological impact on PLWHA leading to low self-esteem and self-stigma that can precipitate development of depression (22, 239). The social aspect of PLWHA is complicated with difficult life circumstances such as public stigma and poverty (173). As a result, several studies indicated that depression can be caused by i) interpersonal problems such as separation, conflict, stigma and loneliness (240, 241), and ii) life changes in relation to the HIV/AIDS such as sickness, unemployment and poverty (18, 25, 242).

The origin of most triggering factors of depression are understood within IPT as mainly social problems that are then the focus of treatment (problem areas) of IPT (229, 231). IPT hypothesises that depression can be treated when social support is enhanced and interpersonal stress is resolved (35). Other scholars suggest including spiritual and cultural components into treatment models of depression (243, 244) and mental health care services (245) since they are important aspects for treatment of many people, especially at the end of life (244). However, further studies are needed on how to address the spiritual elements within IPT specifically for PLWHA in LMICs.

Studies from SSA have shown that depressed PLWHA prefer group-based psychological treatments (96, 147, 150, 231, 241) as these provide supportive environments and help participants to learn new social skills (150, 241). Furthermore, providing or receiving social support during group sessions gives one a sense of belonging and meaning in life (150, 231). Participants report gaining a feeling of acceptance, sense of empowerment and confidence when they are in a group (241). This implies that group-based interpersonal therapy can be a potentially acceptable option for treatment of depression for PLWHA in Ethiopia. Formative studies for adaptation of psychological therapies in Ethiopia have indicated that individual therapy is preferred (246). However, PLWHA seem to be more receptive to groups than individual approaches. PLWHA may feel less stigmatised when they are together with their peers and more able to discuss their psychosocial problems (96). In Ethiopia, IPT has never been adapted for PLWHA. Adaptation is an essential initial step for testing the feasibility and acceptability for this

target population in Ethiopia. This paper focuses on examining the explanatory models of depression and acceptable contexts for implementation of group IPT, such as appropriateness, preferred treatment providers and perceived barriers for the delivery of the group IPT in the HIV care setting. This information is essential for the overall adaptation process.

4.3. Materials and methods

A formative qualitative study was conducted to inform the adaptation of the WHO group IPT intervention. An individual-based IPT training was provided for physicians and health professions to integrate IPT based care at primary health care facilities in Ethiopia (247).

4.3.1. The process of adapting group IPT

The WHO developed the group IPT manual in 2016 (229) to provide guidance on the implementation of group IPT for treatment of depression. The WHO recommends adaptation of the manual for different settings and groups of people. We received approval from the WHO to translate and publish the manual in the Amharic language (Agreement letter TR/18/041). The WHO group IPT manual was adapted over a 5-month period from April to August 2019.

Initially, the authors of this paper reviewed existing literature to identify effective psychological treatments for depression for PLWHA in LMICs (88). From this systematic review we found that interpersonal therapy is effective for treatment of depression especially for people with psychosocial problems. We also learned that there is a culture of conducting group HIV education in our study setting in Northwest Ethiopia. The adaptation process of the group IPT was guided by the ecological validity and culture sensitivity model (111). Furthermore, we used Kleinman's explanatory model of illness to understand broader views of PLWHA on depression (112).

4.3.2. Setting

This study was conducted in FHRH which is located in Bahir Dar, Amhara regional state in Northwest Ethiopia. Bahir Dar is the capital city of the regional state that has a population of more than 750,991 residents. According to the Central Statistical Agency of Ethiopia, 96.8% of the population speaks Amharic as their first language and 93.2% are from Amhara ethnic group. Of the total population in Bahir Dar, 79.7% are Ethiopian Orthodox Christians, 18.47% Muslims, and 1.62% Protestants. FHRH is one of the busiest hospitals in Ethiopia and serves a population of more than 7 million people with 430 beds (248) and 422 health professionals (249). Of the total health professionals, 107 were medical doctors, 174 were nurses and 7 were mental health professionals (248). The hospital records show that 6,251 PLWHA have attended the ART clinic

for their treatment over the last six months. People living with HIV/AIDS play a significant role in the HIV/AIDS care and treatment in the clinic as paid case managers and adherence supporters. Case managers and adherence supporters are HIV positive and they are considered as supportive staffs at the ART clinic. Case managers provide mainly HIV counselling and adherence supporters are responsible for client tracing and home visits.

4.3.3. Participants' recruitment

Eligible participants for focus group discussions were adults who were 18 years old or older and currently receiving ART treatment at the clinic, and included case managers, adherence supporters and users of the services. We aimed to conduct separate focus group discussions in each group. Study participants were assigned into three focus groups: a focus group of case managers (6 participants), adherence supporters (5 participants) and service users (7 participants). For case managers' and adherence supporters' groups, we selected participants who were working on the day of data collection. In addition, for service users' focus group, we selected seven eligible participants randomly (selected randomly at the time they come to the ART clinic for follow up) who were 18 years and above, and not severely ill from the list of participants waiting for treatment on the day of the data collection. Focus group discussions were conducted in a private space in the ART clinic and all of them were led by the first author (BA). All the focus group discussions were conducted in the local language (Amharic) and lasted from one and a half to two hours.

4.3.4. Data collection

We used focus group discussions to collect information from participants. Focus group discussions were chosen because the area that was covered in the interviews was believed to be new to the population particularly discussing the explanatory model of depression and group interpersonal therapy. In addition, focus group discussions can also provide useful information on the feasibility and acceptability of running groups in this setting. Focus group discussions were facilitated using an open-ended interview guide. The interview guide was informed by the framework of Kleinman's explanatory model of illness (232). After initial review, the authors decided to expand the interview guide to include information related to acceptable contexts for implementation of group IPT in the HIV care setting, such as appropriateness of the group IPT and perceived barriers. The interview guide was further revised and translated into Amharic (See the English version of the interview guide in the Appendix D, Module two, section A and B).

We used a case vignette of major depressive disorder to initiate conversation during the focus group discussion (See the case vignette in the Appendix D, Module 2, section C). The case vignette was selected from one of the case studies presented by Sai and Furnham (2013) (250) that was used for detection of depression. The selected case was adapted to the local context by BA and FA and further reviewed by MS. After that, the case study was translated into the local language by BA and it was reviewed by FA for its consistency with the initial case.

The focus group facilitator read the case study (*Mrs. Selam*) of a major depressive disorder twice (see the case study at the annex) and a printed case description was given to each participant to read once before starting the discussion (17 of the 18 participants were able to read and write). Afterwards, participants were asked to give their general opinion about the case of *Mrs. Selam*. Participants were probed to name the problem that *Mrs. Selam* may have, what causes the condition, what other symptoms they know about the condition, its severity, where people with Mrs *Selam's* condition look for treatment and what impacts it could have specifically for PLWHA.

Furthermore, participants were asked to give their opinion on what psychological treatments are and whether they know of any kind of group counselling. Participants were asked for their opinions on the acceptability of group counselling specifically for PLWHA, who could facilitate the group counselling sessions, how the group should be structured in terms of group composition, group size, session frequency and meeting days, how it would be conducted in the ART clinic without affecting the regular service and what barriers could affect the implementation of group counselling in the ART setting in general. The focus group discussions were conducted in a private room which enabled free conversation among participants and provided rich information on the subject matter. Focus group participants were peers (all of them are HIV positive) but were mixed in terms of gender and age, which was a good strategy used to collect valid information.

All focus group discussions were audio-recorded, and the facilitator took notes as needed, for example, to document emotional changes among the focus group participants during the discussion. At the end of the discussion, the facilitator summarised the discussion points and acknowledged all participants for contributing their opinion in the focus group discussion.

4.3.5. Data management and analysis

Audio-recorded data were transcribed verbatim by the first author (BA) and a research assistant (HT) in the local language (Amharic). Afterwards, the transcripts were translated into English and double checked for accuracy. Transcripts were imported into NVivo 12 and data was thematically analysed using a framework analysis. Initially, nodes were created based on the framework of

Kleinman's explanatory model of illness (232). The drafted nodes informed by the framework were naming of the condition, perceived causes, perceived symptoms, perceived severity, impacts of the condition and treatment preferences. We also added acceptability, preferred providers and acceptable context nodes for implementation of group IPT in the ART setting. Sub-nodes emerged from most of the initial nodes. For example, sub-nodes that emerged from perceived cause of depression were biological, psychological, social and spiritual causes. In addition, perceived symptoms were sub-coded as affective, behavioural and somatic symptoms. Word count and word cloud were generated to identify the most important themes. Data coding and theme identification was done by two authors (BA and MS).

4.3.6. Ethical approval

A proposal of this qualitative study was approved by both the University of Cape Town's Human Research Ethics Committee (HREC reference No. 653/2018) and Bahir Dar University College of Medicine and Health Sciences' Ethics Committee (reference No. 007/2018). A permission letter was obtained from the Amhara Public Health Institute. All study participants provided written informed consent. One of the participants was illiterate and she signed by fingerprint after a witness read the written informed consent for her. Refreshments were served during the discussion. Each study participant received compensation to defray transport costs.

4.4. Results

4.4.1. Demographic characteristics of study participants

A total of 18 adult PLWHA (included from case managers, adherence supporters and service users) participated in the focus group discussions. The average age of the focus group participants was 38, 34 and 34 years for case managers, adherence supporters and service users respectively. In terms of gender, one of the six case managers, two of the five adherence supporters and three of the seven service users were male. The average duration of ART treatment was 7.8, 5.5, 7.0 years for case managers, adherence supporters and service users respectively. All case managers and adherence supporters had secondary level education.

Table 11. Socio-demographic characteristics of focus group participants (N=18).

Participants	Gender	Age in years	Educational status	Duration of ART treatment
Case managers	5 females and 1 male	33 – 45	10^{th} grade to 10^{th} +3	3 – 12 years
Adherence supporters	3 females and 2 males	21 – 58	10^{th} grade to 10^{th} +2	2 – 10 years
Service users	4 females and 3 males	18 – 48	From illiterate to 10^{th} +2	2 – 18 years

4.4.2. Explanatory model of depression

a) Naming the problem

Participants debated on naming the condition in the presented case study. Many of them explained that the condition presented in the case vignette is called 'Dibirt' [depression] and 'Ye-Dibirt chigir' [depression problem].

AS3: "We cannot bring another name for this condition, this is 'Dibirt' [depression]. If someone shows symptoms such as timidity most of the time, lost interest in everything and hopelessness in every simple problem so that s/he has depression (Dibirt)". A 58 years old male participant who completed high school education.

CM4: "I think it can be named as 'Ye-Dibirt chigir' [depression problem]. Because the symptoms could be linked with different problems including HIV, imprisonment and any more problems. … Sadness, hopelessness and suicidal ideation appears when multiple problems are occurring on person".

A few participants reported that mental health professionals call depression differently, that is 'Medebet' [similar meaning for depression].

AS1: "In general, I call it 'Dibirt' [depression] but there are people (mental health professionals) who call it 'Medebet'".

b) Perceived causes of depression

The perceived causes of depression reported by study participants included biological, psychological, social and spiritual elements (see Table 12).

Table 12. Perceived causes of depression among people living with HIV/AIDS using biopsychosocial-spiritual model.

Biological	Psychological	Social	Spiritual
• Generalised physical illness • HIV/AIDS • ART medication • Change in body image	• Thinking too much • Excessive worry • Psychological problems • Self-stigma • Witnessing traumatic incident	• Problematic relationship/unfaithfulness • Divorce/separation • Poverty • Family pressure/death of loved one • Conflict • Stigma by health professionals and community members • Failure to succeed • Loneliness • Self-stigma • Sexual abuse	• Evil attack/ spirit possession • Failure to fulfil rituals • Standing on "Atela" [local beer residue], walking on ash

Problematic relationships were the most reported causes of depression as described in the quotes below.

CM6: "Married people could be HIV discordant. One would be HIV positive and the other may be negative. When they get divorced, the one who is HIV positive will have a difficult life. Then s/he becomes very sad, desperate, guilty saying 'I am divorced because I am HIV positive'. They regret a lot, thinking how beautiful their previous life was and finally they could be sick."

AS3: "This could happen because of problematic love. For example, she could be hurt if her husband is in love with another woman somewhere. This would have two problems for Selam. One thing, his unfaithfulness stresses a lot; and secondly, she would have economic problems. All these together would put big pressure on her. If she is economically dependent on him, she will not get a chance to discuss such difficult issues with him. Because she may afraid that he could leave her alone."

Public stigma was commonly reported stressor that is believed to cause depression.

AS2: "… when our kids play with other kids outside home, they have been insulted with bad words such as "Ye-AIDSam Lije" [son of AIDS].

Another participant reflected the same idea in relation to public stigma.

CM4: "… we have unique names in our village which was labeled in relation to our HIV status".

Many of the study participants highlighted that they faced the worst stigma from health professionals, family and from neighbors. The following two quotes show how much health professionals stigmatise PLWHA when providing medical care to them.

CM1: "I faced a similar problem when I gave birth in a hospital. … I was on the couch to give birth. When midwives recognised that I am HIV positive, they put off their gloves and they left me alone on the delivery couch [tear shed]. … Someone requested me to leave the couch and they moved me to the corridor. … In the meantime, labor was pushing, and placenta was descending. … I gave birth at the corridor assisted by one student."

CM3: "Similar to others, I was stigmatised by my family. …I gave birth to a baby girl after I was diagnosed with the HIV/AIDS. I was not breast feeding her and later she was not growing well. She did not gain weight, instead she started losing weight. Afterwards, my family members were blaming me saying 'you infected your baby girl with HIV/AIDS'. … I was stigmatised a lot. I felt lonely, sad, disturbed and worried a lot until she diagnosed negative from HIV."

Many focus group participants associated mental health problems, including depression with spiritual possession and evil attack.

AS1: "People associate the cause of the problem with 'Atela lay mekom' [evil attack while standing on local beer residue], 'Be'amed lay mehed' [walking on ash] and they also link it with 'Ye'aganint likift' [evil attack].

SU1: "Mrs. Selam probably received a ritual tradition from her ancestors. She could be attacked by a spirit When she failed to fulfil the ritual."

Adherence supporters and case managers attributed depression to psychological problems.

AS1: "I believe that we are creating our problems in our mind. … this happens because of our incorrect thinking about ourselves and others."

In relation to biological factors, focus group participants attributed depression to HIV/AIDS and medications. They believe that HIV/AIDS made them sensitive to simple stressors and taking HIV medications for ever makes them become hopeless to enjoy life.

CM4: "There is HIV in our blood which is a big problem. That is why we cannot handle simple problems. HIV/AIDS has an association with our weak psychology. …. I think HIV and depression have a relationship."

AS3: "Taking ART medications is stressful and makes you feel sad. … one of the causes for our stress is the disease itself".

SU4: "Hopelessness comes from taking the ART medications for life long. We are expected to follow a scheduled medication regimen strictly. That is very stressful."

c) Perceived symptoms of depression

The participants predominantly described affective and behavioural symptoms. The affective symptoms predominantly reported were hopelessness, depressed mood, loss of interest, being sad, helplessness, and irritability.

CM1: "…. I was crying day and night holding my baby on my arm. I was extremely sad and worried, no food and drink in my mouth. There were many people around me such as my husband and family were with me, everything was available, but I was feeling hopelessness and helplessness."

Frequently reported behavioural symptoms were loneliness, not eating meals, difficulty sleeping, timidity, being violent, restlessness, sitting in one place for long time, talking slowly, suicidal attempt, looking downward and poor self-hygiene.

CM2: "I have seen Selam's problem on me. I was living and sleeping alone when I was sick. I was not sure I can woke up on the next day. I was saying to myself that I could die while I am sleeping so that I should sleep properly, stretching my legs and hands forward. At least my dead body should be found in a proper position. … I had never eat, I had no interest to eat at all. I felt I was the only person straggling with this much problems in this world. I used to write letters mentioning my father's and mother's name, my uncles' names, their address details, and I put the letter in my pocket when I went to bed for sleep. At least they should know that I died because of natural cause."

Another case manager said, *CM4: I know when clients are depressed. They become angry, irritable, they have no patience, they fight and try to strangulate health professionals with no reason. This is not their fault because they are sick. During interviews, they do not tell us that they are sick but they lose weight from time to time, they are worrying and their behaviour becomes unstable.*

Somatic symptoms were also reported by study participants, such as body pain, headache, hearing a noise in the head as if insects are moving in their head (chichichi) and bell ringing in the head. Cognitive symptoms of forgetfulness and loss of attention were frequently reported by participants.

CM6: " When I was depressed, I used to boil water to pour it on me. I was trying to end my life several times. I used to have chronic headache. … It was a difficult time, I was angry all the time and I used to hear a disturbing noise "chichichi" which looks like insects are moving inside my head. … Now, I suspect depression when clients are behaving inappropriately, when they say 'I lost my card' while holding the card on their hand (when they loss their attention), when they frequently reported forgetting to take their medications."

d) Perceived severity of depression

Participants debated on ranking the severity of the condition presented in the case study. Half of the participants said that the condition was moderate.

AS1: "I would say Selam's illness is moderate. Because, depression comes with one's own problem (fault). Therefore, it should be solved by herself. If she explains her problem to others, she will become fine. She is keeping problems secret. She must start talking then she could improve."

SU5: "Her illness is moderate. Why I said 'her illness is moderate', because she is not crazy like others on the street. What she actually did is just she sat down and think about herself."

The remaining half classified depression as a severe problem. The rationale for classifying the condition as a severe problem was the presence of hopelessness and suicidal ideation in the case study.

SU6: "She (Mrs. Selam) becomes hopeless in life so that her illness is severe. Because hopelessness itself is enough to classify her illness as severe. She is not eating, and she is losing weight. When the hopelessness is added to these, it makes her illness so severe."

AS3: "I would say her illness is severe. She has a wish to die. She would die if she were in the right time and place. Therefore, her illness is severe."

e) Perceived impact

All participants agreed that depression has several impacts at individual and family level, especially when it comes to PLWHA. Most of them reported that the immediate consequence of depression is ART non-adherence which leads to rapid increase in viral load count.

In relation to the impact of depression at individual level, a 35 years old female adherence supporter said, *AS2: "People with depression do not take their medications properly. At the time*

of depression, not only avoiding to take their medication on time but also they dislike to eat meals. At that miserable time of hopelessness, they would prefer to die rather than extending their life a bit longer with the support of medications. Therefore, it is quite obvious that people with depression discontinue their medication commonly."

Similarly, a 40 years old case manager added, *CM2: "… The main impact is on the medication adherence. Medications may not be taken properly. If medications are not taken properly, drug resistance follows, and their viral load increases rapidly. They forget what they are told to do so. … they may take medications twice when they were ordered to take once per day. …. They may skip taking the medications because they think that they already have taken their daily medications. There were people who came to the clinic within ten days after finishing all the medications prescribed for one month".*

Moreover, many study participants described many long-term impacts of depression such as separation, family disintegration, non-functioning and poverty.

SU6: "It is very difficult. HIV/AIDS is affecting our social life especially when it is combined with depression. We distance ourselves from our friends and families. I used to hate my family and myself. I guess I was depressed that time."

A similar idea was reflected from another adherence supporter as follows:

AS1: "First it leads to self-stigmatisation [self-isolation from social affairs] from the community. Second, it leads to economic problems because people with depression cannot work properly. Third, they become incapable to support their family. Afterwards, they may be separated from their family."

Substance use was reported to be one of the long-term impacts of depression.

CM4: "People with depression get into a different life style, for example they may start using substances and drugs. They start cigarette smoking, khat chewing and alcohol drinking habits"

Some other participants reported that the risk of committing suicide is much higher among depressed PLWHA. One of the participants narrated the risk of committing suicide as follows.

AS3: "She (Mrs. Selam) has a wish to die so the impact of depression is clear. She could die if she is not treated on time."

f) Pathways to care

Many participants reported that Holy water/faith healers, witchcrafts and traditional healers are preferred pathways for treatment in the community. Some of the participants believe that bathing or drinking with 'tsebel' (Holy water) – which is a common traditional healing treatment in Ethiopia, could help to treat depression and other mental problems. Holy water is water blessed by a religious father, priest or member of the clergy.

CM6: "When I was mentally sick, I went to Holy water 'Tsebel bet', and I visited traditional healers including witchcraft men several times. Because the community believe that mental problems that are acquired from ancestors or caused by evil attack or spiritual possession can be treated only by Holy water and traditional healers. To be honest, finally, I was treated by Holy water called 'Abune Hara tsebel'".

CM6 continued… *"There is a saying that 'a witchcraft man does not have any treatment for his illness, however the community still prefer to go to witchcraft to get help for mental problems"*

g) Treatment preference

When focus group participants were asked what possible interventions are needed for the condition presented in the case study, all of them spontaneously stated that counselling can be helpful to treat the described case (depression). All of the focus group participants emphasised the need to include psychological treatments with HIV care. Most of them had a basic understanding of psychological treatments and described these in different ways, such as counselling, psychological therapy, talk therapy, active listening and psychosocial support. All focus group participants agreed on the benefits of psychological treatments for depression for PLWHA.

CM4: "What comes to my mind all the time is why psychologists were not included in the team when the HIV care was started. This was a must to include psychologists in the HIV care. I know how many people we lost by suicide, I know how many people became mentally sick and I know how many people discontinued their ART follow up. The past is passed once. But we should start working together for the future."

Active listening was reported as a tool used to engage depressed PLWHA in the process of counselling.

AS3: "Mrs. Selam needs someone who can listen to her. Active listening treats many people who are in trouble and those suffering from excessive worry and sadness."

Another participant added a similar idea.

CM5: "From my experience as a case manager, I came to understand that listening to their problem alone treats half of their condition. …. We come up with solutions together, such as creating a supporting system in every aspect – socially, psychologically and even economically."

Some of the participants narrated that counselling can be as effective as antidepressant medications.

CM6: "I believe that counselling can treat depression as well as the medications. As to me, it is not right to prescribe medications when clients tell us stories such as anger, forgetfulness, and sadness. Medications should be prescribed if and only if counselling failed to treat depression."

This point was further elaborated by another participant:

CM2: "Counselling should come first before prescribing antidepressants. I mean we should provide adequate counselling and see the outcome before giving medication. First, the client should believe in any treatment. Therefore, counselling can help a client to be aware and adhere with any type of treatment."

Many participants believe that peer counselling can help people with depression.

SU3: "A psychosocial group should be established for depressed people as well. Peer-counselling can help to identify solutions for our day to day problems. We can learn a lot from others."

h) Acceptability of Group IPT

Study participants were asked what format of counselling would be preferred by PLWHA and they supported group counselling as can help clients to make decisions and to learn social skills. Some of them described how much they had benefited from a group-based youth HIV counseling programmes a few years back.

AS1: "People with the same problem (HIV) gain energy when they are together. They could solve problems and make decisions together. There is a saying 'Dire biaber anbessa yasir' [a mass of thread can tie a lion] which means you can win any problem when you are together. There is nothing that can make clients afraid to talk when they are in group. Because all of us share the

same problem and all have passed through difficult life circumstances. I believe they will become eager to talk about their life stories during the group sessions."

The above opinion was supported by a number of other participants.

SU3: "I am sure people like the group counselling. It can be acceptable. For example, the psychosocial group helped me a lot when I was a child. I acquired HIV from my mother and I was not aware from whom I acquired it for so long. After I joined group of peers, I have learned a lot. I have got a lot of support from my peers related to HIV/AIDS. Everyone in the group was happy to support me at that difficult time. Moreover, such group counselling programme should be started for adults too."

SU4: "It is a great opportunity when people with the same problem talk to each other. People have a tradition of discussing in groups in this clinic. They exchange ideas with their friends. I believe the approach can be acceptable."

i) Delivering agent

Focus group participants were asked who would be preferred to facilitate group sessions. All study participants strongly proposed the use of trained peer counsellors to facilitate psychological interventions.

AS1: "Peer counsellors can communicate with clients very easily, including with their gestures."

Focus group participants argued that the use of professionals suggests "severe mental health problem" and they were concerned about such labelling.

CM2: "The group counselling you planned to introduce would be great if it is provided by trained peers. Peers can be selected from clients. …… Sometimes, when we take mentally disturbed clients to other professionals, their illness worsens. For example, if I am referred to a psychiatrist or psychologist, I will be worried more and more about the severity of my illness. I may say, 'why they refer me…am I getting crazy?'. … Depressed clients can be treated effectively if they are counselled by their peers. They can get a lot more lessons and problem-solving techniques from peers than from professionals."

One of the focus group participants emphasised on the need to get competent group facilitators to make the intervention effective.

SU4: "There should be a competent person to facilitate group counselling among us. To make the group counselling effective, a better person should be selected to lead the group counselling."

j) Context

Most of the participants suggested that the group counselling should be conducted inside rooms not in open spaces.

SU5: "People may not be comfortable when group sessions are conducted in an open space. Therefore, an ideal meeting space should be selected. The group sessions should be conducted inside a room that should not be accessible by other people who are not a member of the group."

Not everyone was happy on the idea to have separate groups by gender as they felt this was not an acceptable approach. As supported by the quotes below, all focus group participants recommended that men and women be mixed in one group.

AS2 (Female): *"As to me, it is not fair to make a separate group for males and females. Because all are matured and are family leaders and passed through difficult life circumstances. The experience of men and women complements each other and that would be great for the group harmony."*

CM2 (Male): *"I do not completely agree on the idea to have separate groups by gender. I think the mixture of the two genders would be a great tool to facilitate team support. They can share ideas especially on issues related to marital problems."*

However, most participants agreed the need to make separate groups by age. They believe that children (below 18 years old) and adults should be assigned in separate groups. Their rationale for having separate groups by age was because young children may not talk freely in front of adults.

CM3 (Female): *"….. Clients can be categorised by age, such as below and above 18 years old. Eighteen-year-old man can think similarly to 60-year-old man, so they are the same. We should not make too many categories by age difference."*

There was a debate on frequency of sessions and meeting days. Some participants suggested having group counselling sessions once per month and during the weekend days, either Saturday or Sunday. This idea was not accepted by the majority. Many of the participants argued that the

learned skills and techniques of the therapy will be forgotten if the group sessions are conducted every month. They rather suggested to make group sessions at least once a week.

SU2 (Male): *"Having a group counselling once per week for 2 months is simple to attend for me. But what I would advise is the group sessions should be conducted in a place that should be convenient for many of the group members. The meeting place should be chosen with agreement of the group members."*

The weekend days were not accepted by many of the participants. Their concern was related to confidentiality. They debated that coming to group sessions every weekend may elicit questions from people around them.

AS2 (Female): *"The weekend days may not be convenient for many of us. The group counselling should be integrated with regular ART care on the working days from Monday to Friday."*

k) Potential barriers

Participants discussed potential barriers to implementing the group counselling for PLWHA. Lack of transportation access, denial of depression, high case load at the ART clinic, lack of trained staff, stigma and availability of convenient meeting spaces were identified as potential barriers to implement the group counselling.

CM4: "We have clients who are coming from different rural areas far from here. I am afraid that they cannot pay fees for their transportation or they may not have easy access to transportation."

SU6: "People may not accept their illness. They may say 'I do not have depression'. This is a knowledge gap that needs a lot of work to change their attitude. First, they should believe they are sick."

4.5. Discussion

This study investigated explanatory models of depression and treatment contextualisation for depressed PLWHA in Northwest Ethiopia. It is clear that depression has a name given as 'Dibirt' [depression] or 'Ye Dibirt chigir' [depression problem] by most of the study participants. Some study participants reported that 'Medebet' [depression] is a name used by mental health professionals in Ethiopia to describe depression, but they believe that the general population may not understand the term 'Medebet'. Study participants believed that depression has several impacts at individual and family levels for PLWHA, and that it is one of the factors leading to non-

adherence to ART, increasing drug resistance, high viral load, disability, poverty and death. Given this understanding, participants strongly supported the use of psychological treatments for depression among PLWHA.

Important sub-themes emerged from the perceived causes, symptoms and treatment needs. We identified that depression is understood to be predominantly caused by psychosocial problems among PLWHA. Most identified psychosocial problems as the target areas (problem areas) for interpersonal therapy, including conflict, life change and loneliness (35). Our study supports reports of previous studies (211, 251) that PLWHA attribute depressive symptoms to psychosocial problems. The lived experience of PLWHA confirms the inevitable presence of interpersonal stressors, such as conflict within a family, life changes in relation to acquisition of HIV/AIDS and stigma attached to HIV/AIDS, that contribute to the onset of depression (241, 252). The findings of our study confirmed the relevance of spiritual beliefs in relation to the onset of depression that is supported by results of previous studies (243, 244).

In our study, affective symptoms were the main ones with few mentions of somatic symptoms described whereas in previous studies somatic symptoms were predominantly reported by PLWHA (227, 235, 251). Our study participants may have been prompted to focus on affective symptoms of depression after listening to the presented case study. Furthermore, the mhGAP training that some of the participants had received five years back may have helped them to understand depression as an affective disorder. However, most study participants described depressive symptoms from their lived experience.

Study participants believed that peer counselling can be helpful for people suffering from depression. They described their prior experience on a youth HIV counselling programme which brought social support and social connection for many of them. They emphasised the benefits of group-based peer counselling that can help with socialisation and social support. This finding is consistent with previous studies which have reported that group-based treatments have been preferred by depressed PLWHA in sub-Sahara Africa (147, 150, 231, 241) as they enhance social networking, social support and allow participants to learn new social skills (231). Furthermore, they believe that group-based treatments provide feelings of empowerment, acceptance and companionship (241). Study participants perceived the benefits of spiritual treatments such as Holy water for healing and recovery from mental conditions including depression. This indicates that spiritual interventions of any faith and religion could have important implications for treatment of depression for PLWHA in Ethiopia. Therefore, developing/adapting evidence-based treatments

that target psychosocial needs and incorporating spiritual elements into treatment models may improve acceptability and efficacy of psychological treatments particularly for PLWHA. This finding is supported by results from several studies that incorporating spiritual elements with psychological interventions can help to treat severe psychological problems associated with life threatening health conditions (243-245, 253). However, peer evaluation of counsellors, refresher training and regular supervision by health professionals should be in place.

Group IPT could be an acceptable treatment for depressed PLWHA in the ART settings but requires structural and content adaptation within the context of existing health care systems (104, 223). The findings from our study suggest that a strong emphasis should be given to selection of delivering agents and identifying meeting spaces. Study participants from all focus group discussions emphasised that case managers and adherence supporters should facilitate group sessions. Case managers and adherence supporters were perceived as trusted peers and study participants believed that they can understand psychosocial problems of PLWHA. There was some concern that they may not have the competency to deliver the group IPT since most of them had secondary education only. However, several studies have shown successful reduction of depressive symptoms using lay counsellors (96, 131, 138, 141, 148).

The structure of groups was recommended to be age specific. Adults 18 years and above should not be mixed with adolescents. The reason was that adolescents may not feel free to talk about their personal stories in front of adults during the group sessions. However, all men and women study participants recommended the mixing of men and women clients in one group. They believed that mixing men and women can facilitate social support and group harmony. The participants felt that all, including clients and facilitators, should be PLWHA so that common feature would be sufficient to ensure cohesion for mixed groups. This finding is different from the previous study report by Nakimuli-Mpungu and colleagues that groups should be same gender because women may fear to talk their mind in front of men (231). Cultural and educational status of group participants may affect the group atmosphere. For example, in a patriarchal and largely illiterate community, mixing men and women in one group may not be successful.

In relation to group size, six to ten clients per group was seen as acceptable by study participants, with the size of the venue determining the actual size. Large meeting spaces/rooms can accommodate up to ten individuals in one group. However, large group sizes require long session duration to allocate sufficient time for each client, otherwise, the therapy may not be delivered as intended. In terms of session frequency, one group session per week was welcomed by many of

the study participants. Running group sessions every week allows sufficient time for clients to exercise the learned skills at home and it may help them to engage actively in each session. This finding is in agreement with the WHO group IPT guideline and with the previous study report from Uganda (229, 231). With the above conditions, the group IPT could become an acceptable treatment for depression for PLWHA in Ethiopia.

In relation to confidentiality, study participants preferred indoor settings for group meetings as they prevent intrusion from non-members. In addition, as described above, the timing is important to ensure confidentiality, that is not on weekends. Hence, future studies should consider confidentiality issues, such as venue and timing of group sessions, when implementing psychological treatments for PLWHA. Study participants described potential barriers to conducting group IPT in the ART settings. For example, lack of trained facilitators was described as a barrier to conduct the intervention by all/many of the groups. The other anticipated barrier was lack of access to transportation and travel fatigue for group members. This is a practical barrier common to many interventions in low-income countries (84, 254, 255). Arranging meeting spaces in the nearest setting may be an option. However, clients may not prefer the nearest settings to their home due to fear of stigma and discrimination in the community. But lack of transport does mean that interventions will remain inaccessible for the majority of poor and disadvantaged communities.

The ecological and cultural validity model was helpful to generate important findings that informed the adaptation of group IPT as described in the result and discussion sections. For example, it was helpful to, 1) identify acceptable counsellors and approaches used for the intervention, 2) make appropriate language adaptation for the intervention, 3) validate the problem areas of IPT, 4) design intervention methods/strategies. Using the Kleinman's explanatory model of illness within the ecological validity model (233) was found to be an important approach that helps to frame themes for analysis. The conceptual framework contains a set of components that helps to explore clients' perceptions and beliefs about a particular illness. However, understanding some of the items in the model needs good knowledge in the area. This was noticed in this study when the study participants had a challenge explaining biological causes and risk factors for depression. Generally, the model worked well as a guide for this study's data collection and analysis. If Kleinman's explanatory model of illness is contextually used for different illnesses and populations, it can be a reasonable approach applicable to develop and adapt mental health interventions.

Finally, we found that understanding local explanatory models of depression could maximise acceptability and effectiveness of group IPT for treatment of depression for PLWHA in Northwest Ethiopia. Thus, local terminologies used to describe depression such as “Dibirt” [depression] or “Y’Dibirt chigir” [depression problem] should be incorporated into the group IPT manual and other intervention guidelines. In addition, group IPT facilitators should be trained to understand local explanatory models, including the biological, psychological, social and spiritual explanations that local people have for depression.

Limitations

This qualitative study has several limitations that should be noted. Firstly, we used a relatively small number of participants with only one focus group per stakeholder category. Secondly, the study participants may have been biased by the case vignette presented during the focus group discussion. Although there was strong agreement on most of the themes, the results found from *perceived symptoms of depression* may be influenced by the story of the case vignette. Third, our study used focus group discussions for data collection, therefore it may have limited exploration of sensitive issues such as sexual abuse and harassment.

4.6. Conclusion

This study highlighted that a number of psychosocial problems were perceived as contributing to the onset of depression among PLWHA in Northwest Ethiopia. PLWHA believe that depression affects adherence to ART and leads to increasing drug resistance, high viral load, disability, poverty and death. Group-based psychological treatments delivered by trained peers were the preferred intervention approaches for depressed PLWHA. Group IPT was seen as acceptable for PLWHA. However, special attention should be given to the adaptation and contextualisation of the intervention particularly on incorporation of local explanatory models, selection of facilitators, selection of meeting spaces and group structure. We recommend further studies to investigate whether to include spiritual elements with core principles of group IPT especially for PLWHA in Ethiopia. The current study findings will be used to assess feasibility and acceptability trials of group IPT in large HIV populations in Ethiopia.

Chapter 5. Acceptability and feasibility of peer-administered group interpersonal therapy for depression for people living with HIV/AIDS – a pilot study in Northwest Ethiopia

Biksegn Asrat[1], Crick Lund[1,2], Fentie Ambaw[3,4], Marguerite Schneider[1]*

[1]Alan J Flisher Centre for Public Mental Health, Department of Psychiatry and Mental Health, University of Cape Town

[2]Centre for Global Mental Health, King's Global Health Institute, Department of Health Services and Population Research, Institute of Psychiatry, Psychology and Neuroscience, King's College London

[3]School of Public Health, College of medicine and Health Sciences, Bahir Dar University

[4]Department of Psychiatry, College of Health Sciences, Addis Ababa University

My contribution

I conceptualised the study and led the data acquisition, data entry, analysis and interpretation of results. I coordinated all the field work activities, led data entry and data cleaning. I drafted the initial and revised subsequent versions of the manuscript. The three co-authors are all involved as supervisors and provided guidance at all stages and reviewed all drafts of the manuscript.

Note

Please note that this Chapter is a longer version of the manuscript currently under review. The abstract in this Chapter includes more text and the format is edited for the purpose of this thesis to ensure a consistent format of abstracts throughout this thesis. I have also included an extra figure in the Method section and more quotes are included in the result section to better reflect the findings of this Chapter.

5.1. Abstract

Introduction: Psychological treatments are widely tested and have been effective in treating depressive symptoms. However, implementation of psychological treatments in the real world and in diverse population remains difficult due to several interacting barriers. In this study, we assessed the acceptability and feasibility of peer-administered group IPT for depressive symptoms among PLWHA.

Method: We conducted a single-arm, peer-administered, group IPT intervention with eight weekly sessions from 15th August to 15th December 2019 among PLWHA in Northwest Ethiopia. Four IPT groups were formed for intervention with a total of 31 participants. The intervention was provided for PLWHA who had depressive symptoms and were identified from the survey study reported on in Chapter 3.

Results: Of 31 recruited participants, 29 completed the intervention providing a retention rate of 93.5%. The process of the intervention and its outcomes were highly acceptable as most participants expressed success in resolving their psychosocial problems, adjusting to life changes and coping with stigma. The intervention was also reported to be feasible despite anticipated barriers such as access to transportation, perceived stigma and confidentiality concerns. The post-intervention assessment revealed significant reduction in depressive symptoms (mean difference (MD)=9.92, t=-7.82, p<0.001), improvement in PSS (MD=0.79, t=2.84, p=0.009) and quality of life (MD=0.39, t=4.58, p<0.001).

Conclusion: Group IPT is feasible and acceptable and PLWHA can benefit from group IPT in managing depressive symptoms and in improving perceived social support (PSS) and quality of life (QoL). Future studies should examine the effectiveness of group IPT.

Key words: Acceptability, Feasibility, Interpersonal therapy, HIV/AIDS, Ethiopia

5.2. Introduction

Psychological treatments have been widely tested and have shown effectiveness in treating depressive symptoms and other common mental disorders (84, 222, 223, 256). The use of evidence-based and culture sensitive psychological interventions has attracted attention of the scientific community as a result of their promising effectiveness and replicability even in low-income settings (223). Hence, the WHO advocates access to evidence-based psychological treatments for moderate to severe depressive disorders after following proper adaptation procedures (257). However, implementation of psychological treatments in diverse population and in different settings remains difficult due to several interacting barriers during the implementation process (223, 258). Implementation is often undermined by problems related to low acceptability and feasibility of the interventions in a new context (102, 258). Several factors contribute to low acceptability and feasibility, such as lack of resources and access, workload of task-sharing providers, low workforce retention and inadequate levels of competency of delivering agents (102).

In LMICs, common barriers for implementation of evidence-based psychological treatments include: i) lack of adaptation of psychological treatments for new populations (101), ii) low emphasis given to the importance of conducting cultural adaptation for psychological treatments (259), iii) a failure to understand feasibility of the new interventions (260, 261), and iv) low mental health literacy of the community limiting their uptake of the interventions (262, 263).

Psychological treatments may not always need to involve highly skilled health professionals (258). They can be delivered by peer counsellors effectively if appropriate training and supervision is provided (223). However, it is important to establish whether the treatment is acceptable and feasible for a new population and in a new setting. Therefore proper adaptation and systematic harmonisation are fundamental to improving ecological validity, cultural sensitivity and effectiveness of interventions for new populations (104, 264). Moreover, examining the acceptability and feasibility of psychological treatments is crucial before moving into full scale evaluation of effectiveness.

Acceptability is the perception of those receiving the treatment, or any other stakeholders, on whether a given intervention and its outcomes are applicable and satisfactory (223, 258, 265). From a research perspective, it allows us to determine whether an adequate number of subjects will be willing to be recruited for a larger study (89, 265). Feasibility is the extent to which an intervention can be provided successfully for a specific population despite constraints (265). It

examines overall barriers and facilitators to the implementation of an intervention such as applicability (deliverable as planned) and practicality (delivered despite barriers) (266, 267). Feasibility evaluation is particularly important for implementation of psychological treatments in low resourced settings and in communities with different cultural backgrounds where the context of implementation may differ from the one where it was originally developed (266).

IPT, a well-tested psychological treatment in high-income countries, has shown efficacy for treatment of depressive symptoms in a variety of populations (92). A recent systematic review and meta-analysis (reported in Chapter 2 of this thesis) found that group IPT was effective in reducing depressive symptoms in PLWHA in LMICs (88) and a further study (reported in Chapter 4 of this thesis) found that most of the triggering factors for depression were core intervention areas of IPT (109). IPT explores interpersonal problems, finds the link between interpersonal problems and depression, and solves the problem areas (92, 268). The group format of IPT is believed to increase coverage and reduce cost of the intervention (14, 92). Furthermore, it helps counsellors to identify and work on specific problematic communication patterns during interactions among group participants to solve interpersonal problems (92).

In this study, we aimed to assess the acceptability and feasibility of peer-administered group IPT for treatment of depressive symptoms among a selected group of PLWHA in Northwest Ethiopia. We also examined retention rate and the effect of the intervention in reducing depressive symptoms, and improving QoL, functionality and social support by comparing baseline and post intervention assessments. Although peer-administered psychological treatments are widely implemented in a task shifting approach in LMICs (269-271), their acceptability and feasibility have not been explored in Ethiopia. The current study was the first effort to pilot group IPT in an HIV population in Ethiopia. The CONSORT extension to the pilot and feasibility checklist (272) was used to report the findings of this study. Items that were not applicable to this study, such as randomisation and blinding items were omitted as there was no comparable control group.

5.3. Methods

5.3.1. Study design and Setting

A single-arm intervention study with a nested qualitative study was conducted from 15th August to 15th December 2019 with PLWHA who attended ART follow-up appointments during the study period at Felege-Hiwot Referral Hospital (FHRH) in Northwest Ethiopia. We used peer-administered group IPT intervention with eight weekly-sessions for treatment of depressive

symptoms and examined the acceptability and feasibility of the group IPT for PLWHA in Ethiopia. A detailed description of the setting is available in Chapters 3 and 4 of this thesis (109).

5.3.2. Participants

Study participants were recruited from a sample enrolled in a randomly selected cross-sectional survey of PLWHA (N=393) attending the facility from 8th July to 7th October 2019. Results of the survey are published and available in Chapter 3 of this thesis (273). A formal sample size calculation is not appropriate for pilot studies (274), therefore participants were recruited into the intervention consecutively from the survey (273) until sufficient participants were recruited to form four IPT groups. When participants were found eligible for the intervention during the survey (273), they were immediately referred to the group IPT intervention. The survey assessment served as the baseline for the pilot study. Both the MINI and PHQ-9 were administered during the baseline study. But in chapter 5, I used PHQ-9 because, this thesis is built up from the findings of chapter 2, systematic review and meta-analysis, that identified effective interventions for depressive symptoms not for MDD. Moreover, PHQ-9 is more appropriate to measure outcomes of the intervention as a continuous variable than the MINI.

Participants who (i) were adults aged 18 years old or above attending clinical follow-up at the ART clinic of FHRH; (ii) scored five or more on a locally validated Amharic version of the PHQ-9 (275); and/or (iii) were diagnosed with MDD using the MINI were referred by research assistants to group IPT counsellors immediately. Peer counsellors received those clients who had already provided verbal consent to the data collectors. Peer counsellors then took further written consent. In addition, peer counsellors have no role in deciding on the care of PLWHA. Counsellors checked clients' documents for eligibility and approached them to invite them to participate in the intervention. Exclusion criteria for the intervention were (i) being severely sick with a major physical illness or needing urgent medical attention (for example, people with TB); (ii) those identified as being a danger to themselves or others, such as through reports of suicidal or homicidal ideation; (iii) having emotional problems as a result of an organic cause or substance use – detected by research assistants using the MINI exclusion criteria for MDD; (iv) having a major depressive disorder with psychotic or catatonic features; and (v) those who were diagnosed with cognitive deficits or Tuberculosis by ART clinicians or as indicated in the patient's clinical chart. It would be good to include people with TB who completed the initial phase of TB therapy. However, there is a risk of TB treatment failure at any phase of TB therapy which could have a potential risk. The decision to exclude people diagnosed with TB regardless of their treatment phase was made based on a recommendation of counsellors for full safety of group participants.

Group IPT counsellors provided a detailed explanation on the purpose and content of the intervention.

Baseline information of each participant who agreed to join the intervention was then captured into a patient folder. IPT groups were formed as soon as six to ten participants agreed and consented to join the intervention. Group sessions were started within a week after groups were formed. Session days in the week and regular meeting times were set according to the availability of all participants in that group. See figure 14 illustrates how participants were recruited to the intervention. See the standard operating procedure in Appendix F.

At the end of the intervention, we randomly selected a total of 12 group IPT participants (three participants from each IPT group), for in-depth interviews to explore their views on the acceptability and feasibility of group IPT for PLWHA in Ethiopia. We also recruited all of the counsellors (n=6) for a focus group discussion to elicit their opinions on the acceptability and feasibility of the group IPT intervention.

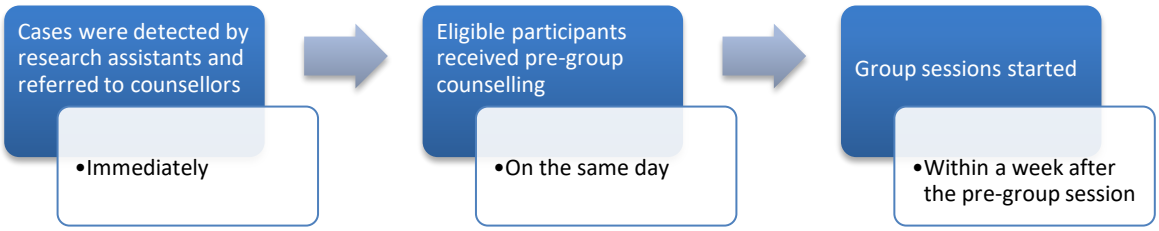

Figure 14. Procedures of recruitment into the pilot study.

5.3.3. Procedures

a) Selection of trainers, supervisors and potential counsellors

Group IPT trainers were selected from the academic staff in the Department of Psychiatry in Bahir Dar University. The selected group IPT trainers were mental health professionals with a Master's level educational background who studied clinical and community mental health for at least 2 years. They had completed the group IPT training of trainers' course and had five to ten years' experience in organising and facilitating mental health training for health professionals. In addition to their academic work, they were also providing clinical services at the Psychiatric clinic in FHRH. They provided the group IPT training for supervisors and potential counsellors in accordance with the adapted WHO group IPT manual (229).

In consultation with stakeholders of the ART clinic, we set the minimum criteria for selecting potential counsellors. These were: a minimum of secondary education (grade 10 and above), being an adherence supporter, case manager, HIV educator or community health worker at the ART clinic, involved in the direct care of PLWHA in the last one year, and being highly motivated to help others. After further discussions with the trainers and supervisors, we decided that the most suitable people to do the counselling were the adherence supporters and case managers. Case managers and adherence supporters were most suitable to provide the intervention because of their shared lived experiences with difficult life circumstances, views about cause and treatment of depression, and to minimise stigma and maintain confidentiality (109).

b) Group IPT training for candidate counsellors and supervisors

A total of 12 people (ten candidate counsellors and two candidate supervisors) received intensive group IPT training for seven days guided by the WHO group IPT curriculum (229). The duration of the training was decided by the group IPT trainers' recommendations. The training was facilitated by four group IPT trainers – two trainers led the morning sessions and the other two facilitated the afternoon sessions. The training included brainstorming, brief presentations, group discussion and many role plays to demonstrate group facilitation skills. Daily training evaluations were conducted at the end of each training day and the trainers adjusted the training to accommodate given comments. At the completion of the training, all trainees took an exit test to assess their level of competency. The test was developed by the WHO group IPT team that included 15-item questions available at the appendix of the manual (229). The score was calculated based on the scoring instruction indicated in the manual as follows: 2 points if the question was answered adequately, 1 point if important information was missing, and 0 if it was not answered correctly. The WHO-IPT guideline recommends that group IPT trainees should achieve a score of at least 70% to effectively facilitate the group IPT intervention (229). Of the ten candidate counsellors, six of them scored above 70% and were recruited to facilitate the group IPT intervention as counsellors. The main responsibilities of counsellors are indicated in Box 5.1.

The two nurse professionals (HT and TG) who were recruited initially with the intention to serve as supervisors were also found competent in mastering the group IPT (scored above 70% on the exit test). The group IPT trainers provided brief supervision training for HT and TG for one additional day after the completion of the group IPT training. This focused on how to conduct constructive and effective supervision, when and how to conduct supervision, how to conduct fidelity assessments for each group session, and when and how to exchange feedback with

counsellors and the PI. Both HT and TG practiced supervision in role plays in front of the trainers before being recruited as supervisors. Each supervisor practiced real supervision in three IPT sessions under supervision of the trainers before conducting supervision independently as recommended in the manual (229).

The main responsibilities of the supervisors were supporting and organising the overall delivery of the project and maintaining contact with stakeholders such as the PI, counsellors and staff members working at the ART clinic. This includes overseeing, monitoring and evaluating the progress of the intervention, coordinating the intervention team, and checking fidelity. Supervisors observed each IPT group during sessions at least every two weeks. They also listened to the audio-recorded sessions and evaluated fidelity of each session. They were also responsible for evaluating group sessions using fidelity checklists, to provide feedback to counsellors and to report to the principal investigator.

Box 5.1. The main responsibilities of peer-counsellors

- Receiving eligible participants, getting consent, conducting pre-group counseling and documenting participants' physical address and telephone number.
- Forming IPT groups, setting a meeting date, time and place.
- Evaluating depressive symptoms of each participant, taking attendance notes.
- Facilitating the group counselling (conducting the problem inventory, encouraging participants to generate possible solutions, make decision analysis, set strategies, providing guidance and counseling).
- Referring clients who refused to participate in the group IPT to supervisors and transferring severely sick or dangerous clients to the Psychiatric clinic.

c) Theory of change workshop

A theory of change can be defined as follows "A particular approach for making underlying assumptions in a change project explicit, and using the desired outcomes of the project as a mechanism to guide project planning, implementation, and evaluation" (276). A Theory of Change workshop was conducted one month before the initiation of the intervention to identify available resources, potential barriers for implementation of group IPT and to design acceptable implementation approaches without affecting the usual HIV care at the ART clinic. Case

managers, adherence supporters, mental health professionals, group IPT trainers, nurses and a unit leader at the ART clinic were invited to attend the workshop. A total of 12 people participated in the workshop (five case managers, three nurses, two adherence supporters, one mental health professional and the head of the ART). Workshop participants explored problems that affect the life of PLWHA, intervention strategies for group IPT, and set assumptions and indicators. The assumption that *managing depression improves social support, functioning and quality of life* was identified as prior conditions to the intervention. The availability of meeting spaces, human resources to be trained as counsellors, and staff good will and motivation were identified as facilitators for implementation of the group IPT. Limited access to transportation, fear of stigma, poor help-seeking behaviour, low understanding by the public about the disabling nature of depression, and illiteracy of most PLWHA (for documenting homework during the intervention) were identified as barriers to the implementation of the intervention. See Figure 15 for Theory of Change map.

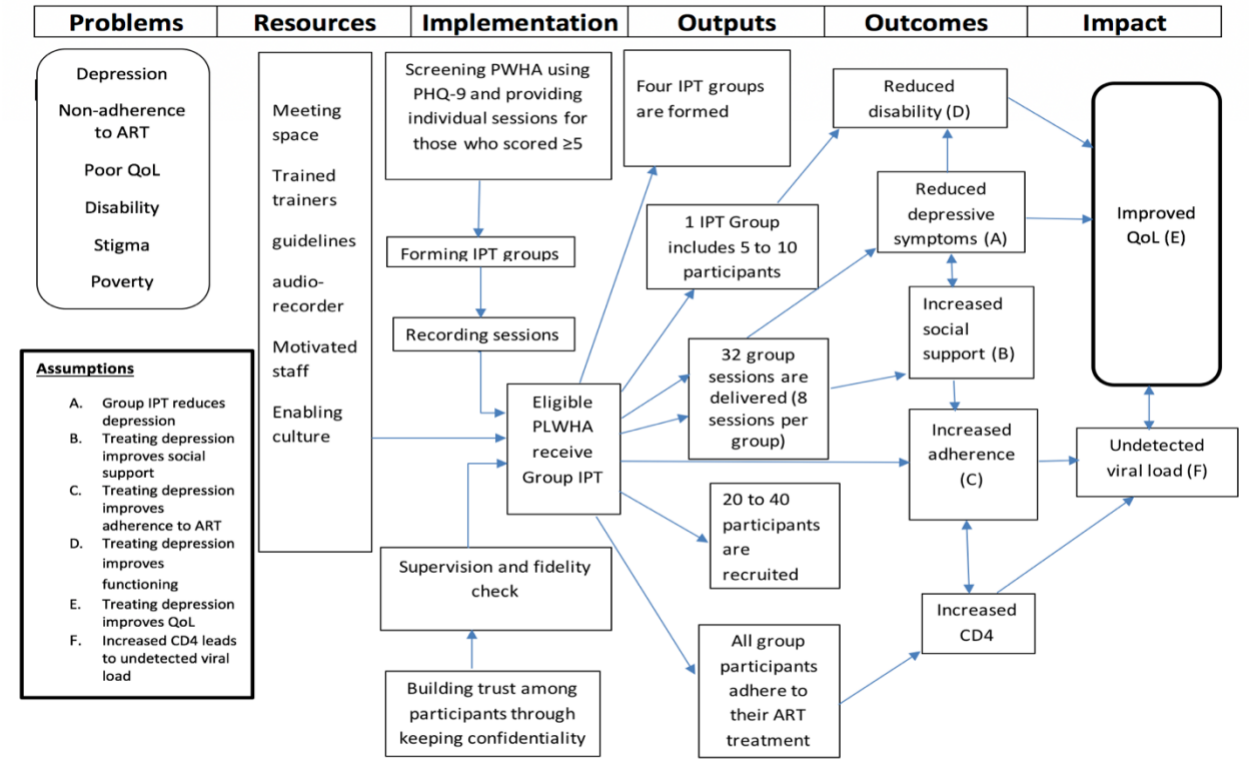

Figure 15. Theory of change on the implementation of group interpersonal therapy for depression for people living with HIV/AIDS.

Note: Post intervention assessment of CD4 count or viral load was not conducted, as it is not likely that significant change in CD4 count or viral load would be observed immediately after two months of a group IPT intervention.

d) Implementation

The intervention was guided by the adapted WHO group IPT manual (109). Prior to initiating the intervention, we completed a substantial process of adapting the original WHO group IPT manual into the local context (reported in Chapter 3 of this thesis). This helped to determine preferred counsellors, group size and dynamics, meeting space and place, and suggested number, duration and frequency of sessions. We followed several steps while conducting the adaptation using the *Participatory and Iterative Process Framework for Language Adaptation (PIPFLA) which is available at the Appendix G* (277). Initially, the original manual was translated into Amharic by HT then back translated by TG. The harmonised document and the original manual were sent to four scientific reviewers (three of them were mental health professionals and one of them was clinical psychologist) for review and their comments incorporated by BA. Finally, a half day adaptation workshop was conducted to further revise the manual. Several stakeholders participated in the workshop such as nurses working at the ART clinic, adherence supporters, case managers, head of the ART clinic and mental health professionals. The final harmonised manual was used in the training for this pilot evaluation.

The intervention comprised of eight weekly 90 minute sessions structured into three phases: *initial, middle and termination phases*. Two counsellors were assigned per IPT group (one mainly documenting and the other leading the discussion, but neither limited to these activities). The sessions were conducted at the ART clinic in rooms arranged to accommodate 10 to 12 people at a time.

Prior to joining group sessions, every participant received pre-group counselling (one individual session). During the pre-group session, counsellors assisted each participant to recognise depressive symptoms, to link their interpersonal problems with depressive symptoms and to set strategies and goals for solving the problems. The *initial group phase* (session one) included a brief discussion on depression and its impacts, and the IPT problem areas (intervention components), followed by presentation of their own depressive symptoms by each participant and exploration of the links between depressive symptoms and the problem areas. In this initial group session, the group members agreed on group goals that should be achieved in the next seven sessions. In the *middle phase* (sessions two to seven) group participants developed strategies to address the identified problems and to implement selected strategies. Depressive symptoms and the links to problem areas were reviewed every week from sessions two to seven. The strategies were evaluated in every session and participants shared stories related to their success to

encourage others. Homework and practical exercises were given every week. In the *termination phase* (session eight), depressive symptoms and problem areas were reviewed, and plans set for each participant. Discussions were held on how to recognise a relapse in depressive symptoms and what they should do when they have symptoms. The implementation phases and respective activities are described in Table 13. Counsellors document the progress of every participant every week on counsellors' weekly note (See Appendix H).

e) Review meetings

The implementation team (counsellors, supervisors and the principal investigator) met every week for an hour. The aim of the review meeting was to exchange feedback, evaluate the progress of the intervention and address challenges that affected the intervention. The meetings focused on enhancing the implementation, for example adherence to the protocol and evaluating decisions made by the counsellors and supervisors.

f) Fidelity of the intervention

All group IPT sessions were audio-recorded for the purpose of fidelity evaluation. At completion of each session, fidelity was rated by the two supervisors (HT and TG) and the Principal Investigator (BA) independently using the WHO group IPT fidelity checklist which is available at the appendix of the manual (229) which is also included in the appendix of this thesis (See Appendix D, module three). Subsequently, identified gaps in adhering to the intervention protocol were communicated to the counsellors in a brief post-session meeting. Discrepancies in the scoring of fidelity items were resolved through discussion with the raters and the PI researcher (BA).

Table 13. The structure of the group interpersonal therapy implemented at the ART clinic in Felege-Hiwot Referral Hospital.

Phases	Sessions	Activities
Pre-group phase	Individual session	• Conducting symptom inventory guided by PHQ-9 items. • Exploring links between onset of symptoms and interpersonal problems. • Providing hope and help clients to join the IPT group.
Initial phase	Session 1	• Facilitate the group members to introduce themselves to each other. • General discussion about depressive symptoms and interpersonal problems. • Facilitate participants to talk about their symptoms and triggering factors. • Set group goals, strategies to solve problems and finalise the session.
Middle phase	Session 2 – 7	• Review symptoms of each participant. • Link depressive symptoms to events from the previous week. • Encourage participants to contribute problem-solving options. • Decision analysis and implement the strategies to achieve the goals. • Providing homework for every participant.
Termination phase	Session 8	• Evaluate number and severity of symptoms. • Make plans, consider referral or consultation if symptoms persist. • Discuss relapse of symptoms and actions to be taken.

5.3.4. Implementation outcomes

a) Acceptability

Group IPT participants were asked to provide their overall views and specific issues on the acceptability of the group IPT intervention. They were asked to provide their views on the number of sessions, session duration, frequency of sessions, competency of counsellors, group size and intervention site. They were also asked to describe their level of satisfaction with the sessions, process of the intervention, competency and approach of counsellors, the convenience and comfort of intervention location, handling of clients' information and confidentiality, and with the outcome of the intervention. They were also asked to rate their level of satisfaction with the overall process of the intervention with a range from very dissatisfied to very satisfied. At the completion of the intervention, counsellors shared their views on the acceptability of the intervention in the interviews, and provided detailed suggestions on an acceptable approach for future use referring to their observations and experience of providing the intervention.

b) Feasibility

Feasibility of the intervention was explored using semi-structured open-ended questions. The questions were framed to explore the following concepts: i) available resources and trained people to carry out the intervention, ii) applicability of the intervention to the larger HIV population, and iii) compatibility of the intervention with existing health service systems. In addition, we calculated the retention rate by dividing the number of participants who completed the intervention by the number of participants who began the intervention to evaluate whether group participants were able to complete the intervention despite anticipated barriers.

c) Depressive symptoms, QoL, functioning and perceived social support

Group IPT participants who completed the intervention were reassessed for depressive symptoms, PSS, functioning and QoL using the PHQ-9, MDPSS, WHODAS-12 and the brief Ethiopian version of the WHOQOL-HIV instruments respectively. PHQ-9 has been widely used in epidemiological studies in Ethiopia. A validation study (unpublished) with an HIV population in Ethiopia reported that a sum score of five and above of the PHQ-9 predicts probable depression among PLWHA. PHQ-9 because, this thesis is built up from the findings of chapter 2, systematic review and meta-analysis, that identified effective interventions for depressive symptoms. Moreover, PHQ-9 is more appropriate to measure intervention outcome as a continuous variable than the MINI (278). Detailed description of these instruments is available in Chapter 3 of this thesis (273).

5.3.5. Data collection

Qualitative data collection and pre-post assessments were conducted by independent research assistants who were trained for data collection purposes only. All of the research assistants were nurse professionals who had prior experience in mental health research with PLWHA and had received mhGAP training. We provided them with a three-day practical training on qualitative and quantitative data collection applicable to the intervention. Qualitative data were collected using audio-recorded individual in-depth interviews of the group IPT and a focus group discussion with counsellors. In-depth interviews were conducted with selected participants from each IPT group at the completion of the intervention as described above. The in-depth interviews and the focus group discussion were aimed at assessing acceptability and feasibility of the group IPT.

At the completion of the intervention the same measures used in the baseline were administered to all group participants to evaluate the status of depressive symptoms, perceived social support,

functioning and Quality of Life. The post-intervention quantitative data were collected by one research assistant who did not participate in any other way in the intervention.

5.3.6. Analysis

A framework approach was used to analyse the qualitative data and to explore the acceptability and feasibility of the intervention. The audio-recorded data were transcribed verbatim into Amharic and translated into English. The translated transcripts were double checked for accuracy and imported into NVivo 12 computer programme for analysis. The data were analysed using predefined themes using a framework approach (279, 280). The themes for acceptability were overall acceptability of the intervention, benefits gained from the intervention, satisfaction with counsellors, acceptability of the structure and process of the intervention. The themes for feasibility were general views on the feasibility of using the intervention for a larger population, barriers to the intervention and strategies to solve the barriers, feasibility of using peer counsellors, and general recommendations. The themes for acceptability and feasibility were selected from core elements of intervention adaptation and implementation science (89, 223, 265) and based on the scope of our study.

Quantitative data were analysed using SPSS version 26. We used descriptive statistics to summarise participants' characteristics and to calculate mean scores. Paired samples t-test analysis was used to compare the scores of depressive symptoms, QoL, functioning and PSS before and after the intervention, and to examine the direction of the change of the intervention. The paired samples t-test analysis was conducted after homogeneity and normal distribution assumptions were fitted in the model.

5.3.7. Ethical approval

The University of Cape Town's Human Research Ethics Committee and Bahir Dar University College of Medicine and Health Sciences' Ethics Committee approved this study. The ethical approval letters are attached at the Appendix (see Appendices A and B). A permission letter was also obtained from the Amhara Public Health Institute. All study participants provided written informed consent. Illiterate participants signed using a fingerprint after a witness read the written informed consent for them. Each study participant received money for transportation to attend group sessions.

5.4. Results

5.4.1. Participants recruitment and retention

A total of 36 clients were approached and 31 of these recruited as participants and assigned into four groups for the intervention within a one-month recruitment period. Of the total participants recruited for the intervention, 29 of them completed the intervention providing a retention rate of 93.5%. Among those who completed the intervention, 28 were reassessed for depressive symptoms, QoL, functionality and PSS one week after the end of the intervention and one participant did not return for re-assessment (Fig 16). One of the participants from group 1, who had a previous history of psychosis, was referred to the psychiatric clinic as she started showing inappropriate behaviour and suspiciousness towards other group members at the 4th group session. One more participant from group 2 was lost after the fifth group session and the intervention team could not find him using his contact address. One of the participants from group 3 who completed the intervention refused to come for re-assessment.

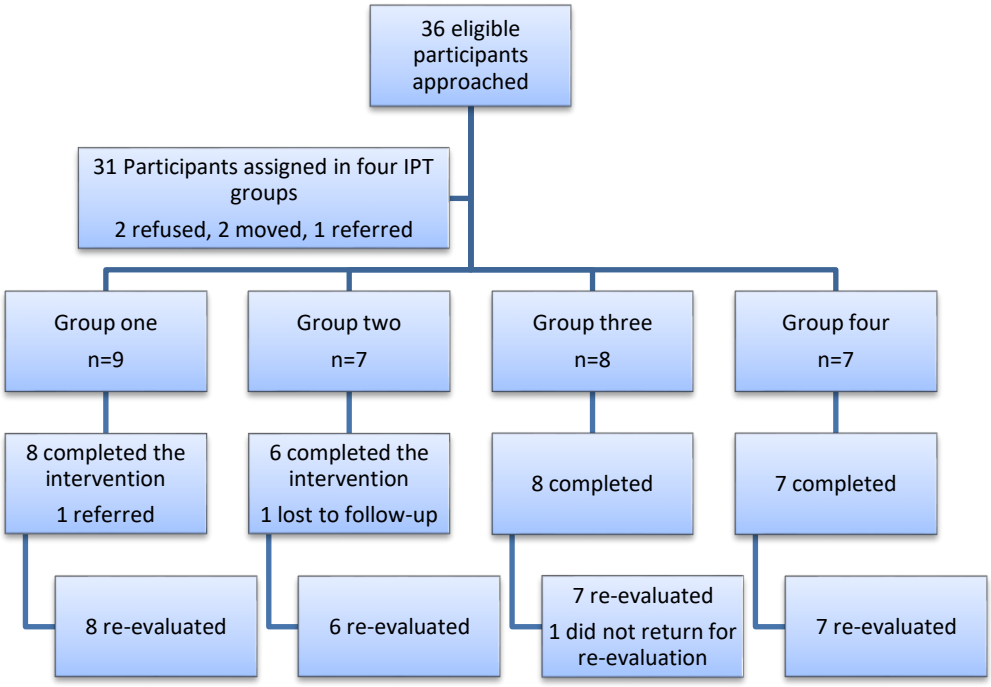

Figure 16. Recruitment, group formation and retention of group IPT participants.

5.4.2. Socio-demographic characteristics of the participants

Of the total recruited participants for the intervention (N=31), three quarters (n=23, 74.2%) of them were women and 41.9% (n=13) were either divorced or widowed. More than half of the recruited participants (n=17, 54.8%) were illiterate and 38.7% (n=12) were unemployed (Table 14).

Table 14. Baseline socio-demographic and clinical characteristics of the group IPT participants (N=31).

Socio-demographic and clinical characteristics		Number	Percent
Age in years	18-29	6	19.4
	30-39	13	41.9
	40-49	9	29.0
	50+	3	9.7
Gender	Male	8	25.8
	Female	23	74.2
Marital status	Single	7	22.6
	Married/ in relationship	11	35.5
	Divorced/widowed	13	41.9
Educational status	Illiterate	17	54.8
	Completed primary education	9	29.0
	Completed secondary education	4	12.9
	Completed tertiary education	1	3.2
Employment	Public servant	2	6.5
	Self employed	17	54.8
	unemployed	12	38.7
Current CD4 count	<200	5	17.9
	200-349	4	14.3
	350-499	5	17.9
	>500	14	50.0
ART treatment regimen	first-line treatment	17	56.7
	second-line treatment	13	43.3
Duration of ART treatment in years	1 - 5	8	26.7
	6 - 10	11	36.7
	11 and above	11	36.7

FHRH – Felege-Hiwot referral hospital; Current CD4 count refers to the recent CD4 count within the last 6 months; IPT – interpersonal therapy.

5.4.3. Acceptability

a) Overall acceptability

All the processes and outcomes of the intervention were generally reported to be acceptable by all of the participants as it is a time-limited intervention with weekly sessions lasting less than two hours. Some of them stated that the intervention facilitated the generation of solutions for social and legal problems such as marital and parental problems, neighbourhood disagreements and conflict in relation to property (for example related to their land or house), psychological problems such as fear of disclosing their HIV status, fear of establishing relationship, and self-stigma.

Note: The codes used along with the quotes below refers to the following. The letter “G” refers to “Group”, “N” refers to “Participant number” and “C” refers to “Counsellor”. For example, “G4N12” refers to “Group 4, participant number 12” and “C4” refers to “Counsellor 4”.

G4N12: "*I really enjoyed the group counselling …. the group was great in generating solutions for problems common to everyone such as disagreement and self-isolation from social participation. That is why I am coming every week to attend sessions.*" (35 year old female).

Most of the participants believe that the existing culture in the community supports group counselling and one of the participants considering "*becoming a counsellor*".

G3N7: "*Our culture supports open discussion and togetherness during difficult times. … I found it much better when it is conducted in a formal way in the clinic. …. I have a diploma in nursing, and I have discussed with my husband about becoming a counsellor. I am confident that I can facilitate group sessions effectively if I can get the counsellors training."* (28 years old female).

Most participants reported that the group counselling was helpful to establish socialisation and friendship.

G2N4: "… *Now, I have got wise and supportive friends. The group counselling has helped me to understand that there are many people who have more severe problems than mine.*" (28 year old male).

Most of the participants agreed that the group counselling was helpful to work as a team on common social problems.

G2N5: *"The group counselling was helpful to work as a team on common problems… people in the group come up with a lot of problems including marital problems, legal and land issues. Group members suggest different strategies to solve each problem. We shared these problems and we tried to solve each of them step by step. We achieved good results in solving such problems in the group.*" (42 year old, male participant).

The diversity of the group participants was perceived to be helpful to find solution for problems.

G4N11: "*Group members were diverse who were better than me... and they were caring like a mother. There were many people who had bigger problems than mine and I reassured myself that my problem was easier to be solved. Solutions were generated when people share their problems with other group members.*" (40 year old, female participant).

However, one of the group participants was disappointed when her comments were rejected by the participants during group discussion but was able to move beyond that.

G1N2: "*Once, I felt disrespected when most of the group participants rejected my opinion. I felt ashamed, sad and tearful. However, it did not stop me from coming to the group sessions. The good thing was counsellors apologised to me for it and they told to the participants to respect each other.*" (32 year old, female participant).

Counsellors also reported that the group IPT was acceptable because it was a medium that encouraged most of the participants to bring change into their lives.

C4: *"The group counselling was a source of motivation for all of the participants. I have been observing a great change in their behaviour and facial expression. They appeared comfortable from session to session – they had warm greetings, free communications, and socialisation with their friends.*" (45 year old, female counsellor).

Another counsellor added that all of the participants were happy and thankful to the group counselling.

C3: "*They did not rush to go home…. they wish to stay with us the whole day …all of them were happy in the intervention and they all thank us at the end of each session.*" (35 year old female counsellor).

b) Perceived Benefits

More than half of the participants reported that the intervention helped them in solving social conflicts and those participants who had not done so, said that the intervention helped them to disclose their HIV status to their family and to be hopeful in their life.

G1N1: "*I had long lasting conflict with one of my neighbours. She (the neighbour) was a pain for me for a long time. Last week, I greeted her, and she hugged me with a smile. I felt as if a big burden has removed from my shoulder. After that day, I am getting good sleep and a feeling of freedom.*" (50 year old, female participant).

The group counselling was helpful to build smooth communication within a family.

G1N2: "*My husband and I used to have disagreement for long time. I used to feel lonely, depressed and even thinking of committing suicide. Now, I have learned techniques on how to have smooth conversation with him despite our disagreement. I have gained confidence, tolerance and calmness to have smooth conversation with him. I have no more anger feelings, sadness and hopelessness. I am very calm, happy and feeling better than before.*" (32 year old female participant).

For others, the intervention helped them in gaining confidence to disclose their HIV status to their family members.

G1N3: "*I used to cry day-in day-out, I used to have severe headache all the time. …. After I attended the first few sessions, I have decided to disclose my HIV status to my closest people. Later on, my pain has gone. I have no shame any more to share my story to others, Thanks to God.*" (37 year old, female participant).

G4N12: "*Before joining the group counselling, I was thinking too much, I used to worry a lot. Currently, I am feeling better, I am sleeping very well. I have started a peaceful life. In addition, I have got an opportunity to meet new people.*" (35 year old, female participant).

Counsellors also reported that they have noticed positive changes in most group participants.

C4: "*I have seen changes from session to session – they become comfortable with group members from session to session. They had warm greetings, free communications, and established good socialisation with their friends which indicates how they all are improving. I am really happy for seeing changes among participants and for being part of the intervention team.*" (45 year old, female counsellor).

All of the counsellors also believed that the group IPT was successful in reducing depressive symptoms of the participants.

C5: "*The group counselling was effective in bringing significant changes. Participants understood what depression is and how it affects their daily lives which is a good thing. We believe that most of the problems that cause depression were managed.*" (58 year old male counsellor).

C6: "*Many of the group participants had similar problems. Most of them had sleep problem, some had poor appetite, some were living lonely and most of the symptoms were resolved.*" (40 year old, male counsellor).

c) Satisfaction with counsellors

All the participants were happy with the competency and skills of counsellors. They said that the peer counsellors could understand common problems of PLWHA.

G2N6: "*I am happy with the counsellors because all of them were our peers who passed through the same difficult life circumstances. They have given us a lot of hope and we feel we can be healthy as they are.*" (55 year old, female participant).

Another participant said that the words of counsellors were encouraging and brought hope in everyone's life.

G4N12: "*They are very supportive like a family – like a mother and a father. … Their word is encouraging and gave us a lot of hope.*" (35 year old, Female participant).

d) Satisfaction with the intervention setting

Most of the participants were happy with the meeting place and space. However, some of them recommended conducting group sessions in a more private place that has minimal social interruptions. One participant said that group sessions can be conducted anywhere but felt uncomfortable to come to the ART clinics due to her "*bad memories*" at the ART. (40 year old, female participant).

G2N6: "*I would appreciate if the group sessions were conducted in "gelel yale" [a bit isolated] and open place, … an open place that has minimal social contact but it should be inside this hospital.*" (65 year old, female participant).

G4N11: "*It can be conducted in open spaces or anywhere that can create relaxing feelings. For example, under a tree or anywhere even in any green area. Then, everyone can feel free to share their ideas.*" (40 year old female).

e) Views on number and duration of sessions

Conducting one session weekly for a duration of eight weeks was accepted by all participants. G3N8: "*… Having one session every week gives us much time to work on our homework. Completing the intervention after eight group counselling is fine with me.*" (44 year old, male participant).

G4N11: "*All was perfect for me. It was not too much not too little, so I do not have any suggestion to be changed.*" (40 year old, female participant).

The 90 minutes session duration was perceived to be sufficient.

C1: "*Sometimes, too long sessions may become boring. There were occasions that some group participants appeared bored during group discussions. I think, sessions were good because we have used an average session duration that can make everyone happy.*" (36 year old, female counsellor).

Another counsellor emphasised the importance of proper time management during sessions.

C5: *"I think the time is sufficient if we are structured and goal directed. I think we should manage the time properly in leading sessions."* (58 year old, male counsellor).

However, some of the counsellors argued that 90 minutes is too short, while most counsellors argued that it was enough to review each group participant's issues.

C4: "*The 90 minutes session duration was short for me to cover all ideas coming from every participant.*" (45 year old female counsellor).

Counsellors were optimistic about the intervention bringing significant change for all group participants. But, they wanted to extend group sessions "*until everyone feels healthy"* and they suggested inclusion of more sessions "*up to 10 or 12*".

C2: "*If our aim is to bring change for every person, we should extend the number of sessions until everyone feels healthy. We have seen great changes with eight sessions but we can solve a lot of their problems if it was extended to more than eight sessions. There were people who were not fully recovered after completing all the eight sessions, they could bring change if it was extended to 10 or 12 sessions."* (33 year old, female counsellor).

C1: "… *One session every week for two months could be fine. Because it gives participants more time to think and work on their homework. I suggest having graduation for those who recovered fully…. But those who did not recover after completing all the eight session should continue taking the intervention. Perhaps, we can mix those whose problem remains unresolved to other groups.*" (36 year old, female).

5.4.4. Feasibility of group IPT

a) General views on feasibility of the intervention

IPT in a group format was perceived to be feasible by almost all participants, as long as it is conducted in an accessible and private setting and an adequate number of peer counsellors are available. Some of them mentioned that the lack of trained peer counsellors could be a barrier to expanding the intervention. To make the group IPT feasible for everyone, a participant suggested making a special arrangement for public employees such as *"conducting one session per month with a longer session duration"*.

G4N11: "*For public employees like me, asking bosses for permission every week may be difficult. Therefore, special arrangement could be made for people who cannot attend sessions every*

week for example, conducting sessions, once per month for longer session duration would be another option." (40 year old, female participants).

G3N7: ***"****The challenge, when expanding this intervention to larger populations may be lack of trained counsellors. … I am confident that the intervention can attract a lot of people. This is something special that has changed my social life."* (28 years old, female participants).

Stigma was a concern for some informants, but they believed that people can learn coping skills after a few sessions.

G4N12: *"Initially, I was thinking like what if people stigmatise me. ….. but later I gained the confidence to face any stigma. It was no more my concern after few sessions, and it did not affect me to come to the group."* (35 year old female).

All the counsellors believe that the group IPT can be feasible *"in involving more people in the future as long as clients are responsive*".

C1: *"The group counselling can be successful and can address more people."* (36 year old, female counsellor).

b) Views on feasibility of using trained peer counsellors

All group participants felt that the counsellors were successful in delivering the intervention.

G1N2: *"… All of them were great facilitators. They took notes and summarise ideas of each participant."* (32 year old, female participant).

One of the informants appreciated the level of the training given to counsellors.

G4N11: "*…. They facilitated group discussions in a professional way. …. To be honest, I did not expect this much knowledge and skill and in them. They were leading sessions as a professional who has intensive experience in counselling. It shows how they were well trained in counselling."* (40 year old, female participant).

c) Experienced barriers

Participants experienced several barriers to attending group sessions such as access to transportation, employment, social responsibilities, sickness and stigma.

G1N1: *"Initially, I thought that I had no energy to come every week because my home was far from the town. Later, I found it a good opportunity to go out of home for a good reason."* (50 year old female).

G2N6: *"Unfortunately, I did not come for two session due to family issues. My daughter gave birth and I was with her to take care of her. I could not come because of social responsibility towards my daughter."* (65 year old female).

Sickness of oneself or a family member was one of the barriers reported by participants.

G3N9: "*I was unfortunate that I skipped the last three sessions because I was sick with kidney disease. I had urgency to urinate and I should go for toileting frequently. That disturbs others which was also against our group rule. Second, the pain could not allow me to maintain my focus fully on the discussion."* (42 year old, male participant).

G3N7: *"I skipped one session because my child was severely sick with flu."* 28 years old, female participant).

Lack of mental health literacy and stigma were also reported as barriers to attending sessions.

G3N9: *"People who have poor understanding about depression may not come to group sessions. They may not expect getting solutions or they may be afraid not be named "chinketam" [an insult for people with excessive worry]."* (42 year old, male participant).

To most of the counsellors, the intervention was completed smoothly, however some of them reported that phone calls were causing interruptions during sessions.

C2: *"We did not face any big barrier to deliver the intervention because every group participant was well organised. I am sure people like to participate in such a lovely counselling programme however it should be accessible to everyone including people in rural part of the country."* (33 year old, female counsellor).

C5: "*Initially, some clients were not silencing their phone calls but later everyone silenced their phone after we included it in the list of the group rules."* (58 year old male counsellor).

In addition, presentation of new and bigger problems in every session by participants affected the process of the intervention to achieve the initial goals.

C3: *"Some problems presented by participants were not achievable in the short term. When we focused on achievable problems, they became less interested and they took the group discussion to the biggest problem that we could not fix it alone."* (35 year old female counsellor).

d) General recommendations received

Group participants recognised the burden of depression in people with HIV/AIDS and they recommended expanding the group counselling programme for a larger HIV population.

G1N2: *"We have been fortunate to be included in the group counselling, however there are many hopeless, sad and depressed people who need urgent help. I recommend you to make this programme accessible to many people."* (32 year old, female).

G2N6: *"There are many people who are in need of help, therefore you all should give them priority. Similar counselling programmes should reach out to others suffering from depression elsewhere."* (65 year old female).

G2N7: *"It should continue and should address more people. You should make it accessible for those who are staying in rural areas."* (28 year old female).

Counsellors also recommended expanding the intervention by involving other stakeholders.

C5: *"It is good to include more stakeholders to expand the intervention and to increase its access for many people. For example, you should consider involving the government because some problems reflected from participants require multisectoral involvement."* (58 year old male counsellor).

C3: *"Yes, it needs collaboration…because some of the problems require involvement of other stakeholders to support these people. Some participants may not have shelter, and some may not have food. Even some may need lawyers to solve their legal problems in courts. I would say most of our clients died not because of HIV but due to psychosocial and financial problems."* (35 year old female counsellor).

C1: *"We understood that depression is caused by life change due to the HIV in many of our clients. Therefore, this intervention should be provided for everyone before starting the HIV treatment."* (36 year old, female counsellor).

5.4.5. Fidelity evaluation

A fidelity assessment was conducted for each session during the implementation phase mainly for supervision purpose and to provide feedback to the counsellors. Failure to adhere to the protocol was communicated to counsellors in weekly review meetings. Generally, counsellors were evaluated as being satisfactory in adhering to the protocol. A Likert scale checklist was used to evaluate fidelity. Each items of the checklist contained six responses options from a score 1 "not assessed" to 6 "excellent". The mean fidelity scores were 5.30 (0.38), 4.91 (0.62), 4.78 (0.54) and 4.93 (0.39) for group 1, group 2, group 3 and group 4 respectively. The average mean score of fidelity for all IPT groups was 4.98 (0.19) which can be interpreted as satisfactory based on the rating references in the group IPT manual (229). Some gaps in fidelity to the protocol were identified by supervisors. These included skipping the interpersonal inventory, failure to prioritise problems, forgetting to link interpersonal problems with onset of depressive symptoms, failure to work on a specific prioritised problem and changing the intervention goal as driven by participants interest.

5.4.6. Depressive symptoms, QoL, functioning and perceived social support

The mean PHQ-9 depression scores reduced significantly between baseline and post-intervention (mean difference (MD)=9.92; t=-7.82; p<0.001). The mean PSS scores (MD=0.79; t=2.84; p=0.009) and the mean QoL scores (MD=0.39, t=4.58, p<0.001) improved significantly between baseline and post-intervention. However, there was no statistically significant difference in mean scores for functioning between baseline and post-intervention (MD=1.27; t=0.70; p=0.492) (Table 15).

Table 15. Paired t-test analysis, change in depressive symptoms, quality of life, perceived social support and functioning (N=28).

Outcome	Baseline mean score	Post group IPT mean score	Mean difference	t	95%CI	P value
Depressive symptoms (PHQ-9)	16.77 (6.74)	6.74 (4.62)	-9.92	-7.82	-12.54, -7.31	<0.001
Functionality (WHODAS-12)	36.81 (8.99)	38.08 (8.09)	1.27	0.70	-2.48, 5.02	0.492
PSS (PSS-12)	4.63 (1.36)	5.43 (0.92)	0.79	2.84	0.22, 1.37	0.009
Quality of life (WHOQOL-HIV-BREF-Eth)	3.23 (0.50)	3.67 (0.51)	0.39	4.58	0.21, 0.56	<0.001

5.5. Discussion

This study was the first to pilot the acceptability and feasibility of group IPT for treatment of depressive symptoms for PLWHA in Ethiopia and group IPT was perceived as being an acceptable and helpful intervention in addressing psychosocial problems and in reducing

depressive symptoms. The process of the intervention and its outcomes were judged to be highly acceptable for three reasons: first 93.5% (n=29) of the participants completed the intervention; second most participants reported benefit from resolving psychosocial problems such as marital and family conflicts, adjusting to life changes and coping with stigma; and third, the intervention created good opportunities for participants to establish friendships, learn social skills and gain social support. In addition, the context of the ART clinic with a highly stable workforce and the process of consultation on the need for and implementation of the intervention together with stakeholders, may have contributed to this positive outcome. This positive finding may also be because of the use of peer counsellors, an accessible intervention setting, and reimbursement of transportation costs. Moreover, establishing good therapeutic alliance during pre-group sessions can also have contributed to engaging the participants in the group sessions. This finding is supported by a randomised controlled trial from Uganda that demonstrated high acceptability and effectiveness of group IPT with an excellent acceptability (only 7.8% dropout rate) (90) and findings of other studies from LMICs (92, 96, 281). The interpersonal theory that hypothesises that IPT can decrease interpersonal stress and enhance social support through improving social skills, emotion processing and resolution of interpersonal problems (35) seems to hold true for the HIV population.

The structure of the group IPT with a total of eight weekly group sessions was acceptable. However, some counsellors wished to increase the number of sessions to 10 or 12 to ensure that all participants improved. Many previous studies have used up to 16 or more weekly sessions which could be important in producing long-term benefits (282). The use of an extended number of sessions is time consuming, labour intensive and resource demanding – and may also suffer from low acceptability. The high cost and low availability of trained personnel in LMICs encourages the use of adapted psychological interventions that are brief, structured and simple to be delivered by peers or lay counsellors rather than the complex interventions that demand more resources and time (283). However, attention should be paid not to miss core elements such as the four IPT problem areas when adapting group IPT and other interventions (284).

Peer-administered group IPT was acceptable to the group IPT participants, as they felt that peer counsellors can understand psychosocial problems of PLWHA and were happy with the skills and competency level of the counsellors. However, they emphasised that supervision should be in place. This is supported by previous findings that peer counsellors successfully deliver psychological interventions (88, 223). The randomised controlled trial from Uganda successfully

used trained community health workers as counsellors who were also accepted by the community as they have a common understanding and shared world view on depression (90, 92).

Most of the participants were comfortable with the ART clinic setting, although one stated that she felt uncomfortable to come at the ART clinic due to *"bad memories*". The ART clinic setting was probably in the most accessible location for residents in the town and it was chosen to maintain confidentiality and minimise stigma (109). Therefore, the integration of mental health services such as group IPT within the services provided by the ART clinic seems an acceptable approach.

Generally the group IPT was found to be feasible for use in larger HIV populations which is in agreement with reports of previous studies in LMICs (92, 96, 281, 285). However, it is important to note that several barriers could affect its implementation. Access to and cost for transportation, sickness, stigma, social factors and public employment were the main challenges that could affect similar interventions. Most of these barriers can be addressed in designing special arrangements and with strong commitment of the clients and counsellors. This includes deployment of adequate numbers of trained counsellors and high commitment of clients in minimising social barriers.

From the quantitative results, we found a significant reduction of depressive symptoms, and improvement in PSS and QoL at the post-intervention assessment. These findings need to be viewed with caution given the lack of a control group. Nevertheless, the quantitative findings were supported by in-depth interviews with group IPT participants – most of them said that they benefited greatly from the intervention. The significant reduction in depressive symptoms and improvement in QoL is supported by findings of several randomised controlled trials in LMICs (90, 104, 282), suggesting that increased social support mediates depressive symptoms that can lead to improved QoL. There was no significant improvement in functioning at the end of the intervention. The comorbidity of HIV/AIDS with depression could have a bigger effect than HIV/AIDS alone on functioning that may not be improved with group IPT alone.

IPT has been extensively examined and widely used for treatment of depression in high income countries. The basis for IPT is interpersonal theory which makes a practical link between mood disturbance and problematic life events (286). In principle, IPT considers depression as a medical illness (286), however it does not specifically address biological risk factors. Thus, it has limited therapeutic scope for depression caused by biological factors, since its foundation is built on only interpersonal aspects of life. Despite its limitations, IPT has been found to be potentially effective, acceptable and feasible as a therapeutic intervention, which is supported by rich evidence in other studies (125).

There are arguments among scholars on acceptable treatment approaches of IPT. On the one hand, scholars argue that a group-based approach is more acceptable and feasible than the individual-based approach (14, 90), while on the other hand, others favour individual-based intervention (246). The findings in this study indicated that, despite its implementation barriers, group-based IPT can be an acceptable and feasible approach for PLWHA in Ethiopia. Common challenges for implementation of group-based IPT in low income settings may include, 1) structural problems such as inconvenient intervention setting, and 2) unsupportive model of care such as health systems unfavourable to the integration of group-based interventions into the existing services. Implementation of group-based IPT could also be challenging when there is lack of trust among the therapeutic team and if confidentiality becomes a concern for clients. The cost of the intervention could also be a challenge but that needs further cost analysis studies. However, cost wise, different studies authored by well-known global mental health researchers favours group-based intervention (14, 287).

Finally, the participants strongly recommended expanding the intervention in collaboration with other stakeholders such as with the government, non-governmental and charity organisations. Without collaboration, the intervention will remain inaccessible and limited to those who are located near the intervention setting, and who can afford paying transport costs. Moreover, accessibility and affordability should be a priority when replicating psychological treatments including group interpersonal therapy.

I believe that the findings of this study are trustworthy. Qualitative data were collected from a range of participants and both focus group discussion and in-depth interviews using theory-based frameworks. In addition, quantitative data was collected using structured and validated instruments. Focus group discussions and in-depth interviews were conducted by trained and independent research assistants. I conducted rigorous framework-based qualitative analysis to maintain the credibility and trustworthiness of the results. I, the principal investigator had no role in facilitating group sessions and in conducting any of the post-intervention interviews.

Limitation

Despite its important findings, our study had several limitations that should be considered while interpreting the results. First, our study had no control group which makes the observed change difficult to interpret as it is difficult to control the natural course of depression and other confounders. Second, the sample included in the pilot intervention was small as the main aim of the study was to explore the acceptability and feasibility of the group IPT. Third, the outcome

assessments were conducted at the place where therapy was delivered and that could have led to social desirability bias from respondents. However, we used independent data collectors for the baseline and post-intervention interviews to minimise the social desirability bias. Fourth, it is important to note that the post-intervention assessment was conducted immediately after the completion of the intervention and so longer-term impacts of the intervention cannot be assumed.

5.6. Conclusion

The intervention procedures and strategies of group IPT delivered by peer counsellors seemed acceptable and feasible for PLWHA in Ethiopia. PLWHA can benefit from a group IPT intervention in treating depressive symptoms in low-income settings. We recommend future studies to focus on examining the effectiveness of peer-delivered group IPT using randomised controlled trials.

Chapter 6. Discussion

In this chapter, I summarise and discuss findings in relation to the aim of this thesis and the strategies I followed to adapt and pilot the intervention in the HIV care setting in Ethiopia. This is followed by a discussion on the implications of this study for the field. Finally, the limitations of the thesis are discussed, and the recommendations presented.

6.1. Summary and discussion of findings

6.1.1. Effectiveness of psychological treatments for depressive symptoms in LMICs

Chapter 2 presents the systematic review and meta-analysis of trials of psychological treatments that were aimed at managing depressive symptoms among adult PLWHA in LMICs. The current systematic review and meta-analysis was helpful for drawing conclusions in areas such as in identifying effective psychological treatments and treatment providers and formats of interventions for adult PLWHA in LMICs. The included studies used different interventions either in a group or individual format in community or institution settings. The studies were heterogeneous in terms of sample size, outcome measures and type of intervention. The main findings of the systematic review and meta-analysis were: i) studies that used psychological treatments that focused on resolving psychosocial problems were effective in reducing depressive symptoms; ii) trained and supervised non-specialist counsellors can deliver psychological treatments effectively; and iii) both group and individual-based interventions were acceptable and effective.

In a sub-group analysis, trials administered by non-specialist counsellors were found to be effective (88). The use of trained non-specialist counsellors helps to efficiently utilise human resources in a task shifting approach (98), and has been widely advocated to reduce the gap in mental health care in LMICs (98). In LMICs, one of the contributing factors for the huge mental health treatment gap has been reported to be the scarcity of highly skilled human resources such as psychiatrists, psychologists, social workers and mental health professionals (65, 74). The use of supervised non-specialist counsellors in a task shifting approach seems an important and effective approach for low resourced settings that can contribute to closing the mental health treatment gap. The “friendship bench” programme in Zimbabwe (108) and the GSP in Uganda (287) have shown the global community that the use of non-specialist counsellors in administering psychological treatments has been successful in enabling access to basic mental health services in low-income countries.

Chapter 2 found that both group and individual-based interventions were effective and there was no difference in effect size between the two intervention approaches. Group-based interventions have been commonly used in LMICs and are reported to be acceptable in a number of African cultures (92). Group-based interventions are particularly important to establish therapeutic alliance, develop social support and build social skills (94, 288, 289). Group-based interventions enable the increase in access to basic mental health interventions for large groups of people at a time (92). Individuals are not alone in groups, and it is also easier to change people's negative thought patterns in groups than in individual-based interventions (94). This argument is supported by the findings presented in Chapter 4 of this thesis that PLWHA preferred group-based counselling such as group IPT over individual-based counselling. This is further supported by the findings from Chapter 5 of this thesis that indicate that group IPT was found to be an acceptable intervention for PLWHA. The post-intervention evaluation in Chapter 5 indicates that participants felt that their problems were recognised and heard by others. The social support and reassurance they got from group members helped them to solve their psychosocial problems. The experience they gained from others assisted them to disclose their HIV status to their family members and helped them to trust other people. In addition, the observed reduction in the score of depressive symptoms, significant improvement in PSS and QoL in Chapter 5 of this thesis shows the potential effectiveness of group IPT for PLWHA with depression in Ethiopia.

6.1.2. Burden of depression and areas for psychological intervention

In Chapter 3, I examined the prevalence of MDD using the MINI diagnostic instrument and assessed its association with adherence to ART and QoL among PLWHA in FHRH in Northwest Ethiopia. I also identified socio-demographic and clinical factors that are associated with the MDD, adherence to ART and QoL. The prevalence of MDD was 32.5% and the indicated prevalence was comparable with findings of other previous studies in SSA, such as 28.7% in Nigeria (290), 34.9% in South Africa (291), 24.7% in another study in South Africa (292), and 40% in western Uganda (293). However, the 32.5% prevalence of MDD indicated in Chapter 3 was higher when compared to findings from other similar studies in SSA such as 2.7% in rural Tanzania (294), 8.1% in semi-urban areas in Uganda (41), and 9.6% in Zambia (295). There are big differences in the prevalence of MDD between the study findings, although all of the above studies used international diagnostic criteria, mainly the MINI. The reasons for the observed wide variability in the prevalence of MDD seems to be very complex. Judd and colleagues argued that it is difficult to draw a clear conclusion about the prevalence of depression as long as methodological variations between studies exist and the characteristics of study populations are different (296).

This is further explained by Simoni and colleagues who stated that culture plays a central role in shaping the experience and language used to describe depression (22). Using international diagnostic criteria to diagnose MDD may not be ideal due to cultural differences across different populations and every individual being unique (22). Simoni and colleagues emphasised the “emic” perspectives that propose that depression research must address cultural differences and pay attention to the validity of measures critically when using these in different populations. Another reason for variation is that few studies have used gold standard measures of depression, which would be semi-structured clinical interviews administered by psychiatrists or clinical psychologists. Fully structured diagnostic interviews, as used in this study, are known to have validity problems. Whatever variations exist between several studies, nevertheless, MDD remains the most common mental disorder in HIV populations, and affects the treatment outcome of HIV/AIDS and the overall QoL of PLWHA.

Social and psychological problems play an important role in causing and triggering depression among PLWHA, such as problematic relationships, divorce or being a widow, lack of social support, stigma, loneliness, unemployment and poverty, which were all associated with MDD (Chapters 3 and 4). Previous studies also indicated that social problems are risk factors for depression (14, 41, 297, 298). PLWHA are affected by several psychosocial problems (299, 300) such as the diagnosis of HIV/AIDS leading to distress as HIV is incurable, and this is then followed by the fear of rejection by important people, the fear of losing loved ones and the fear of infecting other people (300, 301). Low self-worth, self-stigma and non-disclosure increases vulnerability to developing psychiatric symptoms such as depression (239). For example, a longitudinal study in China found that HIV-related stress is highly associated with depressive symptoms (298). Moreover, the disclosure of HIV status remains profoundly limited as PLWHA are afraid of exclusion from their socio-economic participation in their community which increases their vulnerability to depression (301). In addition, people with advanced stage of HIV/AIDS suffer from physical pain and psychological distress such as helplessness, hopelessness, worthlessness and low mood (22). HIV/AIDS-associated adverse life events, food insecurity and poverty can cause depression (41). Clinical factors, for example, advanced stage of HIV/AIDS (298) and functional disability (302), can also lead to the onset of depressive disorders among PLWHA.

Most of these determinants are core problem areas of IPT. Interpersonal theory identifies four core principles (problem areas) that can both cause and maintain depression: dispute or conflict, life change, grief, and loneliness or social isolation (286, 303). External, developmental and interpersonal problems can increase interpersonal stress, reduce social support, and create

emotional difficulties, and these factors can trigger or maintain depression (91). IPT can treat depression by resolving interpersonal problems, improving social skills, reducing social stressors and enhancing social support (35). This is supported by previous studies in SSA that demonstrated the effectiveness in treating depression using IPT (92, 96). Verdeli and colleagues argue that depression due to excessive worry and difficulty to fulfil basic necessities (due to poverty) can also be managed using group IPT (31, 92, 150). In addition to psychological interventions, PLWHA need poverty alleviation interventions such as assistance with employment, income generation and housing support (14).

6.1.3. Selection of a psychological treatment for piloting

A candidate intervention was chosen based on the results from Chapters 2, 3 and 4. These were: i) findings of the systematic review and meta-analysis in Chapter 2 suggested that psychosocial treatments such as IPT are beneficial for the treatment of depression; ii) findings in Chapters 3 and 4 showed that depression among PLWHA in Ethiopia maps onto all four problem areas of IPT: life change, conflict, grief, and loneliness or social isolation; and iii) findings from previous studies on depression among PLWHA in Ethiopia indicated that psychosocial problems are important areas for intervention (18). Most importantly, social problems such as divorce, separation, stigma, a lack of social support and loneliness are important determinants of depression. All of these factors can be addressed by using IPT (35, 229). Finally, IPT was chosen for this study to assess its acceptability and feasibility for the treatment of depression for PLWHA in Ethiopia. The availability of IPT guidelines, already trained IPT trainers and other resources, including favourable infrastructure (space and private rooms) to conduct the intervention, were facilitators in choosing IPT for piloting. The preferred mode of delivery of the intervention was in group format due to the following conditions: i) group-based interventions are as effective as individual-based interventions (see Chapter 2 of this thesis); ii) group IPT is a manualised, time-limited and structured intervention; iii) social skills and coping strategies can be learned between the group members (304); and iv) group IPT was reported to be a low cost intervention that can be delivered by non-specialist counsellors (14).

6.1.4. Adaptation of group IPT manual

In Chapter 4, I described the adaptation of group IPT for PLWHA in Northwest Ethiopia using the Ecological Validity and Culture Sensitivity model (111). I conducted focus group discussions among HIV counsellors (case managers), adherence supporters and service users to explore their perceptions about the causes, burden, severity of depression, and pathways that PLWHA

are using to receive mental health treatment (112). I also explored their views on the structure of group IPT, length of each session, group size and dynamics, preferred delivering agents and preferred intervention settings. These findings are incorporated into the adapted version of the WHO group IPT manual, which served as a guideline for training counsellors and for the intervention.

The findings in Chapter 4 show that depression is viewed mainly as an outcome of interpersonal and psychosocial problems, and that these problems can be defined within IPT. The main recommendations drawn from the content adaptation of the WHO group IPT were: i) to include both men and women in forming IPT groups and with five to ten people per group; ii) to meet in private and quiet rooms; iii) a session length of between 1.5 to 2 hours conducted weekly; iv) membership of the IPT groups to be closed (not to include new members into the established IPT group after the first group sessions).

Subsequent to the content adaptation, translation and language adaptation were conducted for the WHO group IPT manual (229) by incorporating the findings described above using a stepwise Participatory and Iterative Process Framework for Language Adaptation (PIPFLA) approach (277). PIPFLA is a tool (framework) that guides how to undertake language adaptation for culture-sensitive manualised psychological interventions. It includes several steps to conduct the adaptation to manuals and different intervention guidelines. The PIPFLA indicates that language adaptation for intervention manuals should be started by forward and backward translation followed by cultural adaptation involving stakeholders. Harmonisation and validation are also important steps of PIPFLA that finally help to use acceptable, appropriate and clear language for interventions. The PIPFLA framework allows the researcher to conduct a stepwise, descriptive and participatory language adaptation for a manualised intervention which is grounded in principles of good practice. It was a useful approach that helped to include appropriate, culturally acceptable and clear terminology into the manual through the participation of stakeholders. The process of language adaptation for the WHO group IPT manual involved translation, back translation, expert review and harmonisation steps. The recommendations drawn from the content adaptation were included into the manual, such as who the preferred counsellors are, the IPT group size and dynamics, the preferred intervention setting, and the intervention duration. Adaptation of the manual was made within the areas that the WHO recommended for adaptation. The core elements of group IPT and techniques of the intervention described in the original WHO guideline were maintained in the adapted manual as all of them were found to be valid to our study population The adapted manual was written in a simplified language to be used by non-

specialist counsellors, and several modifications made to improve its cultural relevance. The adapted manual was also reviewed by stakeholders in a one-day adaptation workshop to validate the cultural relevance, clarity, applicability and acceptability of the language used in the manual. Several stakeholders participated in the workshop, including case managers, adherence supporters, ART nurses, mental health professionals and a psychologist. After the harmonisation of feedback obtained from the workshop, several copies of the manual were printed and used for training and the intervention.

Although, the core principles of IPT are important areas for intervention, some authors argue that all of them may not be necessarily important (92). However, our study findings presented in Chapter 4 found that all the four problem areas are valid for PLWHA in Ethiopia. Previously, group IPT was adapted and used by Bolton and colleagues in HIV-affected communities in Uganda (90, 92). Available global evidence showed that group IPT was cost-effective when used with a broad range of people with MDD in clinical settings (305). Bolton and colleagues indicated that group IPT could be more relevant to African cultures – because the view of oneself as being part of a family and a community is particularly strong in Africa (92). In the adaptation of the group IPT, Bolton and colleagues found that three of the four problem areas of IPT were associated with depression but that loneliness and/or social isolation were not applicable as a cause of depression in the HIV-affected community in Uganda (92). Their study participants were recruited in the HIV-affected area, but their HIV status was not known so that stigma may not have been a concern. In the absence of stigma, loneliness or social isolation may not be viewed as a problem since the established social network and social support continue working in the community. In their field trial, Bolton and colleagues used 16 weekly group sessions and each session lasted for 90 minutes (90). While the WHO does not provide reasons for recommending a limit of eight weekly sessions (229). these could include to i) maximise its acceptability, ii) increase its cost-effectiveness, and iii) save time and other resources.

The other important finding in Chapter 4 was to include both men and women in forming IPT groups which is believed to facilitate social support among group participants. This is in contrast to several group-based intervention trials from Uganda which matched group participants by separating men and women (92, 231). The other important finding indicated in chapter 4 was the recommendation on meeting place. Most PLWHA preferred the ART clinic settings rather than places in the community due to the fear of public stigma, concern about confidentiality, and easy access. But the studies conducted in Uganda used any meeting place available in the community and were more flexible in this regard (90). Confidentiality and stigma may not be an issue for

participants in Uganda, therefore, the meeting place may not be a concern for them, but it is a very important issue for PLWHA in Ethiopia.

6.1.5. Acceptability and feasibility of group IPT

Chapter 5 presented findings of the pilot study including the acceptability and feasibility of peer-administered group IPT for depression among PLWHA. The overall evaluation of the pilot study indicated that the procedures and outcomes of group-based IPT were acceptable and feasible. The eight weekly group sessions of up to two hours duration were accepted. This is in agreement with the findings presented by Nakimuli-Mpungu and colleagues in the development of a culturally sensitive GSP intervention in Uganda, that adult PLWHA preferred group format counselling to individual-based counselling. The group-based interventions are thought to assist in expanding social networks, social support and coping skills (231). Nakimuli-Mpungu and colleagues have successfully implemented the GSP in HIV populations as a result of its high acceptability (287). Group-based IPT delivered by community health workers in a task shifting model was also found to be acceptable for PLWHA in South Africa (150). Petersen and colleagues adapted non-specialist administered group-based IPT in 12 weekly sessions for PLWHA in South Africa (96) and they found the intervention conducive for delivery using a task shifting approach.

As indicated in Chapter 5, the adapted group IPT delivered over eight weekly sessions provided encouraging results, which attest to the feasibility of peer-administered group-based IPT for PLWHA with depression in Ethiopia. Findings suggested that implementing group-based IPT in a more private and accessible setting encourages the participation of clients due to minimal exposure to stigma and favours maintaining confidentiality. It is always important to be flexible when choosing intervention settings and this should be done in consultation with the stakeholders and PLWHA. Trained peer counsellors were the most trusted and respected agents who contributed to the high acceptability and feasibility of peer-administered group IPT as shown in Chapter 4 of this thesis (109). Peers (case managers and adherence counsellors) have a close supporting relationship with PLWHA and are their sources of motivation (306).

Physical accessibility was perceived to be an important barrier that can affect the acceptability and feasibility of the intervention when used for larger populations. Most PLWHA live in poverty (307) and may not afford travelling costs to get mental health treatment. Moreover, others who live in rural areas may not have easy access to transportation to attend sessions every week. In this case, either the participants should be funded for transportation costs or the intervention should be disseminated to every primary health care setting and integrated into other HIV

services. Conducting group sessions in villages within the community may reduce travelling and can increase participation in the intervention, if stigma can be minimised and confidentiality maintained to ensure acceptability.

The lack of trained peer counsellors was also perceived to be a barrier to the intervention. Currently, there are 486 active case managers and adherence supporters in the Amhara regional state (in Northwest Ethiopia) working at ART clinics supporting PLWHA providing HIV counselling. In every referral ART clinic, an average of 15 case managers and adherence supporters are working along with health professionals to improve the lives of PLWHA in Ethiopia. Most of the case managers and adherence supporters received basic WHO mhGAP training that focused on detecting and managing common mental disorders. This highlights the availability of human resource potential that could assist in integrating peer-administered psychological interventions such as group IPT into the HIV care settings, especially given the encouraging results from the current study.

6.1.6. Strategies contributing to the high acceptability and feasibility of group IPT

In this section, I reflect on some of the processes of engagement that were conducted prior to and during the implementation of the intervention in collaboration with different stakeholders and that seem to have contributed to the positive outcomes of this study. These included i) a systematic and participatory cultural adaptation of group IPT; ii) stakeholder ownership and team motivation; iii) skill-focused training on group IPT; and iv) supervision and team organisation. I believe that these efforts contributed to enhance the acceptability and feasibility of a group IPT intervention among PLWHA in Ethiopia. I will present a brief description on each point below.

The cultural adaptation of the group IPT intervention was conducted with the full participation of stakeholders whose recommendations were valued and taken into consideration during the adaptation of the WHO group IPT to the local context. The manual used simple language that is culturally appropriate and clear to service users, counsellors and supervisors. The opinion of each person was recognised when harmonising the manual and this assisted in establishing trust among the research team and service users. A selection of potential counsellors, determination of IPT group size and dynamics, number and duration of sessions, and time and date of meetings were made through collective decisions by stakeholders from the ART clinic.

Creating stakeholder ownership and efforts to getting their motivation were done prior to launching the implementation. A sense of ownership was established as the stakeholders started understanding the commitment of the researchers on the project. A spirit of collaboration, trust

and teamwork were established among counsellors, supervisors and data collectors. The motivation created among counsellors was a great asset for the success of the intervention. Counsellors were the engines of the intervention who created a sense of belongingness within the team. Every counsellor was eager to see changes among group participants at the end of every session. The commitment of the counsellors to their given role greatly motivated the clients (group participants) to complete the intervention (93.5% of the participants completed the intervention).

The skill-focused group IPT training provided to counsellors and supervisors was a fundamental asset in implementing the intervention successfully. The group IPT training was designed based on the WHO group IPT manual recommendations and in consultation with group IPT trainers. Ongoing adaptation of the training was done through daily reviews and discussion of the training by trainees and trainers. The aim of the training was mainly to teach the skills of facilitating IPT in group format, and the content of the training and the method of delivery were evaluated before the training days. The skill-focused training and the involvement of stakeholders in designing and conducting the group IPT training contributed to getting competent counsellors who had great motivation to help others.

Supervision and good team organisation were central to the successful implementation of the intervention and were made possible by the commitment of the research team to the project. The team was organised based on the given roles, the roles of counsellors and supervisors were clearly stated, and everyone was supervised in his/her responsibilities. The counsellors were responsible for starting sessions on time, facilitating sessions successfully and completing session notes. The supervisors were responsible for coordinating and organising the overall process of the intervention, supervising, and evaluating the reliability of the intervention. I, the principal investigator (a mental health practitioner), also played a role in arranging logistics and organising the whole team. I provided consultation for any difficulties such as diagnosing severely ill clients, making referral decisions and linking clients who had other medical conditions to other treatment services. Other than these roles, I had no direct involvement in the decisions made by the counsellors and supervisors in relation to the intervention to avoid researcher bias.

The implementation of psychological treatments usually needs trust-building and buy-in among stakeholders. This needs more effort, particularly in communities where psychological treatments are perceived to not be important (308) and with people with low mental health literacy (263). Internal challenges within the implementation team, such as resistance, and external barriers,

such as the presence of unsupportive policies, can affect the outcome of interventions. Inadequate funding, a lack of trained counsellors, limited supervision and a lack of collaboration can influence the acceptability and feasibility of treatments (309). Strong supervision, high commitment and coordination are important strategies for delivering psychological treatments effectively. More importantly, high motivation to help others, good communication skills and good organisational skills are highly needed for the successful implementation of group IPT. All these steps and time required to achieve effective buy-in and build mental health literacy require sufficient funding, but they pay off in the long term and should not be ignored.

The unprecedented occurrence of COVID-19 would have affected the implementation of group IPT due to the nature of the infection that spreads in gatherings. Conducting group sessions using other approaches such as running group sessions virtually could be a good solution, although it is less likely to be applicable for people living in low-income settings, including in Ethiopia. Other alternatives should be found when such difficult conditions interfere with the implementation of group IPT.

Generally, the findings of this thesis believed to be credible, dependable, transferable, trustworthy. The study was designed to answer specific research questions and implemented with active engagement of stakeholders using scientific guidelines and theoretical frameworks. Data were collected by using trained and independent research assistants using mixed data collection methods and validated instruments. Qualitative and quantitative data analysis were conducted guided by theoretical frameworks and using up-to-date analysis models. The results were interpreted in a way that is understandable to researchers and policy makers.

6.2. Limitations

There are several limitations that should be considered when interpreting the findings of this thesis. Specific limitations from Chapters 2 to 5 were addressed explicitly in each chapter's limitations section. The general limitations of the thesis include: i) the diagnosis of MDD in Chapter 3 was made by nurse research assistants which may lead to false positive or false negative diagnoses; ii) the findings used to adapt the WHO group IPT indicated in Chapter 4 may not be generalised to all PLWHA in Ethiopia; iii) the use of focus group discussions in Chapter 4 to explore perceived causes for depression have limited the collection of information on sensitive issues such as on intimate partner violence (IPV); iv) the significant reduction in depressive symptoms and improvement in PSS and QoL in Chapter 5 may not show the real effectiveness

of the intervention due to the absence of control groups. Each of these limitations is discussed along with their implications in detail below.

First, the diagnosis of MDD in Chapter 3 was conducted by trained nurse research assistants which may introduce a false positive or false negative diagnosis of MDD. A false negative diagnosis may result in the missing of real cases in the intervention. Ideally, the diagnosis of MDD should have been conducted by a psychiatrist from the local population. However, psychiatrists are scarce in Ethiopia and the number of psychiatrists per 100,000 population was reported to be 0.08 in 2017 (74). There were only two psychiatrists serving in the hospital in a part-time capacity during the data collection period. Therefore, using psychiatrists for data collection was not feasible and would not be realistic in a scale-up effort either. I am a mental health practitioner who is licensed to diagnose and prescribe medications. Thus, I provided training to nurses to administer the structured instrument of the MINI depression module by including several role-plays in the training. Nurses were chosen to administer the MINI because they had completed a psychiatry course during their nursing training and had received WHO mhGAP training. Moreover, I provided close supervision and assistance during the data collection. The use of trained nurses to diagnose MDD using the MINI has also been in practice in similar studies in Ethiopia (194). Although all necessary precautions were made when administering the MINI, the diagnosis conducted by nurses may still have introduced false diagnoses of MDD. Producing more psychiatrists takes more time and it is less likely that this gap can be filled in the next few years in Ethiopia. Preferably, this can be dealt with through the provision of adequate training to capacitate research assistants in diagnosing common mental disorders, including depression.

Second, the findings that were used to adapt the WHO group IPT indicated in Chapter 4 may not be generalised to all PLWHA with different cultures in Ethiopia. Ethiopia is a diverse and multi-ethnic country which contains more than 80 ethnic groups with more than 86 languages (310). I translated and adapted the WHO group IPT manual into the Amharic language which is spoken by more than 90% of people in the Amhara regional state in Northwest Ethiopia and serves as the working language for the Federal Democratic Republic of Ethiopia (FDRE). The adapted manual can be used by Amharic speakers who are familiar with the Amhara culture. Therefore, readers should consider that the cultural adaptation conducted for the WHO manual may not be generalisable to the larger HIV populations in Ethiopia. More research is needed to sufficiently address PLWHA representing different cultures when adapting group IPT in other parts of Ethiopia.

Third, the use of focus group discussions in Chapter 4 to explore perceived causes for depression have limited the collection of information on sensitive issues. IPV, HIV/AIDS and mental health are three problems affecting a third of women of any age globally, and the most affected people are women from Africa (311). IPV is recognised as a major social problem that has been reported to have a strong association with depressive disorders (312, 313). A high prevalence of IPV has been reported as being common among HIV-affected people in Ethiopia (314). However, IPV or any other form of domestic violence and abuse were not elicited from any of the focus group participants in Chapter 4. The participants may not disclose sensitive issues including IPV during focus group discussions and IPV may remain hidden due to the use of focus group discussions in exploring perceived causes for depression. This can be managed using different data collection approaches in future: for example, including individual interviews or conducting separate focus group discussions with women alone can help to elicit information on sensitive issues including IPV.

Fourth, the aim of Chapter 5 was to explore the acceptability and feasibility of group IPT for depression for PLWHA and some tentative effects of the intervention but without control groups. Therefore, the significant reduction in depressive symptoms and improvement in PSS and QoL in Chapter 5 may not be real effects of the intervention as there was no control group with which to compare the outcomes. But these initial results provide an indication of possible trends and could assist in calculating required sample sizes for full trial to test the effectiveness using a control group. Hence, future studies need to examine the effectiveness of group IPT in reducing depressive symptoms and in improving PSS and QoL for PLWHA using randomised controlled trials.

6.3. Recommendations

6.3.1. Recommendations for mental health researchers

Despite the limitations discussed above, this study established a strong foundation in generating knowledge on depression treatment for PLWHA and in adapting group IPT for PLWHA in Ethiopia. The stepwise and evidence-based approaches used in this thesis provide good examples of how to adapt psychological interventions using implementation science which can serve as baseline evidence for future studies aimed at adapting similar interventions in Ethiopia.

However, more research is needed to unfold the problems that cause depression in PLWHA, to identify evidence-based psychological treatments that can effectively address depression, and to explore approaches used to adapt evidence-based treatments into local contexts. The established

evidence on the effectiveness of psychological treatments has been limited to trials that included a limited number of psychological treatments. Some of these trials lack methodological rigor in drawing conclusions on whether a specific intervention is effective or not for PLWHA in LMICs (131). These findings call for researchers to conduct more randomised controlled trials to answer what type of treatment, in what context and what dose is effective for depressive symptoms for PLWHA. Such studies could also consider the suitability of IPT- versus CBT-focused interventions within an African context. Assessment of cost effectiveness should also be an important research area which is highly relevant to determine the economic feasibility of interventions. There is also a lack of evidence on how to adapt evidence-based psychological treatments for PLWHA in LMICs. The WHO drafted a protocol that can be used to adapt psychological treatments for different cultures, and future studies could improve the drafted protocol for standardised use in LMICs (113). This multi-step protocol can be used by researchers to adapt psychological treatments for several mental disorders including for depression in LMICs. The WHO group IPT manual found to be an excellent guide written in clear and simple language that included all the important IPT components along with clear procedures. The manual is big in size and needs a significant effort to translate and adapt it. However, the main recommendations drawn from this thesis are that adaptations of group IPT should start with an understanding of the communities' conceptualisation of depression, examining perceived causes, exploring treatment traditions. Recognising the traditional healing strategies and harmonising the new intervention into existing healing approaches can increase the acceptability and feasibility of the intervention. When adapting group IPT, researchers should give special attention for group dynamics, group size, intervention setting, contexts and session structures.

The results of the pilot study presented in Chapter 5 showed significant change in reducing depressive symptoms and increasing social support and QoL within the immediate period after the intervention. This shows that group IPT has good potential as an effective psychological treatment for depression for PLWHA in Ethiopia. In addition, the findings presented in Chapter 5 established the acceptable conditions of group IPT and how to make it feasible. IPT is not new to Ethiopia. IPT trainings have been provided by Ravitz and colleagues to physicians and health professionals in some parts of Ethiopia in collaboration with the Biaber project (247). Ravitz and colleagues suggested that medical education that involves IPT can contribute to narrowing the mental health treatment gap in Ethiopia through accessing basic psychological interventions (247). However, there has been no trial conducted to examine the effectiveness of IPT, particularly among PLWHA in Ethiopia. Research is required to examine the effectiveness of

group IPT using randomised controlled trials. It is also important to explore useful approaches to integrating group IPT into more ART clinic settings in primary, secondary and tertiary health care services in Ethiopia.

6.3.2. Recommendations for HIV care providers

The findings presented in this thesis have implications for recognising the magnitude of depression in the HIV population and for understanding the usefulness of psychological treatments, including group IPT, in managing depression and in improving the life of PLWHA. The findings presented in Chapter 3 show that one third of PLWHA had MDD, which is much higher when compared to other findings from SSA. This calls for the timely treatment of depression to facilitate clients' engagement with HIV treatment and help to improve QoL of PLWHA (315). The role of the work force at ART clinics in Ethiopia, including health professionals and non-specialist HIV care providers, is highly important in the management of depression because treatments of depression can be provided by non-specialists who have received basic mental health training with strong supervision and support (78).

The findings in Chapter 5 indicate that most HIV counsellors (case managers and adherence supporters) in Ethiopia received mhGAP training and can therefore contribute to the treatment of PLWHA with depression. Peer-counsellors were preferred by PLWHA to facilitate group sessions using a task shifting approach (Chapter 4). A task shifting approach seems a good strategy for addressing the shortage of highly trained human resources and can offer high quality and cost effective care to PLWHA (316). The Lancet global mental health series has strongly recommended the use of a task shifting approach to address the huge mental health treatment gap in LMICs (317) and in order to use available human resources efficiently (318). The WHO has also made important recommendations on the implementation of a task shifting approach, with particular emphasis on the need to train non-specialists, treat common mental disorders and retain the approach (319). Therefore, the stakeholders at the ART clinics need to follow evidence-based implementation approaches and should recognise the role of case managers and adherence supporters in addressing depression if they have favourable working environments. Most importantly, the heads of ART clinics in Ethiopia need to provide private space for counsellors who help facilitate group sessions. It is also important to provide supervision and training on group IPT for peer-counsellors.

6.3.3. Recommendations for policy makers

Policy makers need to understand the burden of depression and its impacts on the overall wellbeing of PLWHA. The mental health treatment gap in the general population is likely to be much higher in PLWHA in Ethiopia, and this suggests the need for mental health policy, political will, strong leadership and collaborative effort. Depression needs more emphasis due to its huge health-related and socio-economic impacts on PLWHA. Peer counsellors can feasibly facilitate group IPT interventions with a high level of acceptability, which is also supported by findings from LMICs (148). Peer counsellors can be selected from case-managers and adherence supporters. The number of case managers and adherence supporters is inadequate in Ethiopia (320). Hence, policy makers need to develop policies and strategies that can enable the delivery of task-shifted health care services in every ART clinic in Ethiopia. Producing more case managers and adherence supporters, and training them in group IPT, can contribute a lot to addressing depression in low-income settings.

6.4. Conclusion

This thesis sought to adapt and pilot group IPT for the treatment of depression for PLWHA, and to examine its acceptability and feasibility in ART clinics in Ethiopia. The thesis further examined the magnitude of MDD and its association with adherence to ART and QoL, as well as explored the perceived causes of depression among PLWHA. This thesis found that PLWHA are vulnerable to depression due to psychosocial adversities associated with the diagnosis of HIV/AIDS, such as problematic relationships, interpersonal conflict, divorce/separation, stigma, loneliness and poverty. This thesis identified different types of psychological treatments that can help reduce depressive symptoms, although their effectiveness varies. Psychological treatments that focus on addressing psychosocial problems were effective for PLWHA in LMICs. The findings presented in this thesis indicate that IPT can be therapeutic for depression for PLWHA in Ethiopia. Group IPT was found to be an appropriate, acceptable and feasible intervention that can help promote social support, establish therapeutic alliance, enable the learning of new social skills, and enhance motivation for change among intervention participants. The overall findings from the cultural adaptation of WHO group IPT indicate that this intervention was highly feasible and was perceived to be acceptable when delivered through eight weekly sessions of 1.5 to 2 hours.

The Ethiopian health system strongly advocates for accessing mental health interventions using a task shifting model. A task shifting model enables the movement of tasks from highly skilled professionals to trained non-professionals. In this regard, peer counsellors can take over the roles

of psychologist and mental health professionals after receiving group IPT training and can contribute to making basic mental health interventions accessible to PLWHA. Peer counsellors were acceptable to PLWHA and found to be important agents for providing the group IPT intervention. The use of peer counsellors, with a strong supervisory and referral structure, seems a cost-effective approach that allows the efficient use of human resources in providing access to mental health care services for a larger number of PLWHA. Peer counsellors can speak the language of the community and deliver the adapted group IPT successfully.

The integration of mental health care into HIV care services should be a priority in addressing depression. Integrated mental health services can increase access, improve client satisfaction, and help to provide all services at a time in one place, which reduces referrals. The integration of mental health services into primary health care has been promising in Ethiopia but needs a continuous supply of trained human resources and consistent availability of medications (321). In times of shortage of trained human resources, the introduction of peer-administered group IPT can help to narrow the huge mental health treatment gap using a task shifting approach. Nevertheless, psychological treatments need cultural adaptation, acceptability and feasibility assessments and testing of effectiveness prior to wider scale-up. In this regard, group IPT has shown good acceptability, feasibility and potential effectiveness in managing depressive symptoms among PLWHA. Thus, the next step for researchers should be taking the group IPT intervention through a full randomised controlled trial to examine its effectiveness in treating depression and improving PSS and overall QoL. Treating depression leads to better ART adherence and hence less reliance on second line ART medications. This, in turn, leads to better individual health and public health outcomes.

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Appendices

Appendix A. Ethical approval from University of Cape Town

Ethics approval for the present study obtained from the Human Research Ethics Committee (HREC), University of Cape Town.

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: Sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

27 September 2018

HREC/REF: 653/2018

A/Prof M Schneider
Alan J Flisher Centre for Public Mental Health
46 Sawkins Road
Rondebosch

Dear A/Prof Schneider

Project Title: DEPRESSION AND HIV/AIDS: ADAPTING AND PILOTING GROUP INTERPERSONAL THERAPY FOR TREATMENT OF DEPRESSIVE SYMPTOMS FOR PEOPLE LIVING WITH HIV/AIDS IN NORTHWEST ETHIOPIA (PHD Candidate - Mr B A Yirdaw)

Thank you for your letter to the Human Research Ethics Committee dated 19 September 2019.

Please comment on the referral /help pathway for those who are found to remain depressed. Please include details in the Informed consent documents.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

Yours sincerely

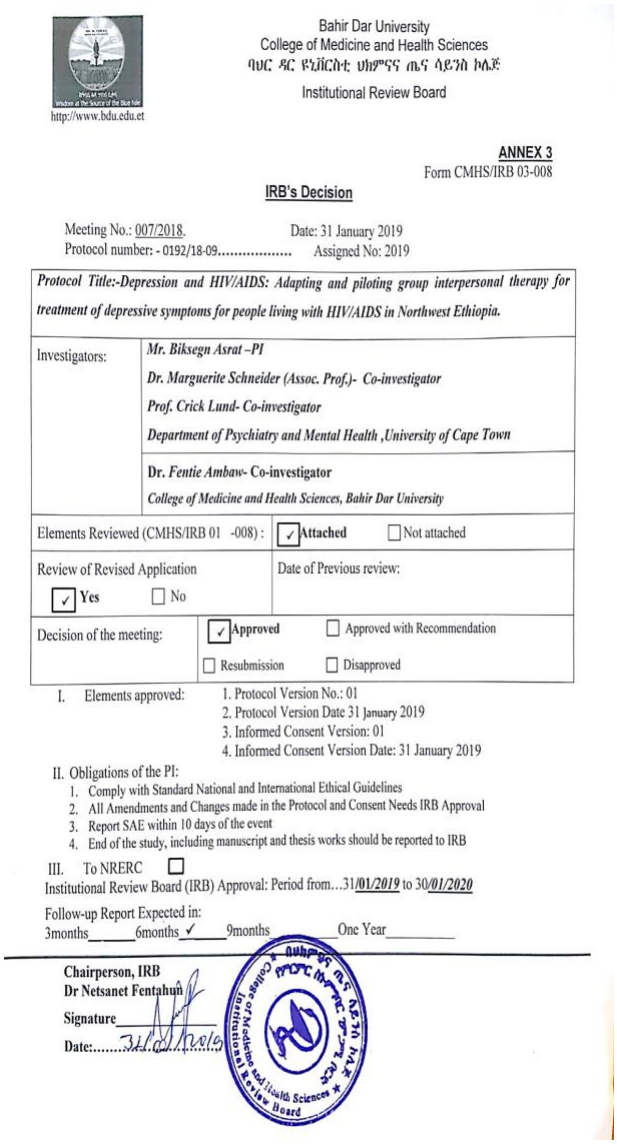
pp ZBurgess

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Hrec/ref:653/2018

Appendix B. Ethical approval from Bahir Dar University

Ethical approval for the present study obtained from the College of Health Sciences, Bahir Dar University.



Bahir Dar University
College of Medicine and Health Sciences
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Institutional Review Board

http://www.bdu.edu.et

ANNEX 3
Form CMHS/IRB 03-008

IRB's Decision

Meeting No.: 007/2018. Date: 31 January 2019
Protocol number: - 0192/18-09..... Assigned No: 2019

Protocol Title:-Depression and HIV/AIDS: Adapting and piloting group interpersonal therapy for treatment of depressive symptoms for people living with HIV/AIDS in Northwest Ethiopia.	
Investigators:	*Mr. Biksegn Asrat –PI* *Dr. Marguerite Schneider (Assoc. Prof.)- Co-investigator* *Prof. Crick Lund- Co-investigator* *Department of Psychiatry and Mental Health ,University of Cape Town* **Dr. *Fentie Ambaw*- Co-investigator** *College of Medicine and Health Sciences, Bahir Dar University*
Elements Reviewed (CMHS/IRB 01 -008) :	☑ **Attached** ☐ Not attached
Review of Revised Application ☑ **Yes** ☐ No	Date of Previous review:
Decision of the meeting:	☑ **Approved** ☐ Approved with Recommendation ☐ Resubmission ☐ Disapproved

I. Elements approved:
1. Protocol Version No.: 01
2. Protocol Version Date 31 January 2019
3. Informed Consent Version: 01
4. Informed Consent Version Date: 31 January 2019

II. Obligations of the PI:
1. Comply with Standard National and International Ethical Guidelines
2. All Amendments and Changes made in the Protocol and Consent Needs IRB Approval
3. Report SAE within 10 days of the event
4. End of the study, including manuscript and thesis works should be reported to IRB

III. To NRERC ☐
Institutional Review Board (IRB) Approval: Period from...31/**01/2019** to 30/**01/2020**

Follow-up Report Expected in:
3months_____6months_✓_____9months_____One Year_____

Chairperson, IRB
Dr Netsanet Fentahun
Signature_____
Date:.....31/01/2019

College of Medicine and Health Sciences Institutional Review Board

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Appendix C. Approval for inclusion of publications in the present thesis

Dear Biksegn Asrat

I hereby confirm that the Deputy Chair of the Doctoral Degrees Board has **approved** your request to include 3 publications (and 1 paper in review) in your PhD thesis.

In your thesis (after your declaration that it is your own work) please include the following separate signed statement listing the publications that you were given permission to include:
"I confirm that I have been granted permission by the University of Cape Town's Doctoral Degrees Board to include the following publication(s) in my PhD thesis, and where co-authorships are involved, my co-authors have agreed that I may include the publication(s): "

This declaration serves to notify examiners that the Doctoral Degrees Board has granted you permission to include publications in your thesis.

Kind Regards

JANINE ISAACS
Doctoral Degrees Board Officer

UNIVERSITY OF CAPE TOWN
Room 5.04 I Masingene Building I Cross Campus Road I
I Middle Campus I Rondebosch I South Africa I 7700
Doctoral Candidates Webpage
+27 (0) 21 650 2202

Appendix D. Questionnaires, interview guides and checklists

(Note: all Amharic translations are available on request from the author.)

Module one: Structured questionnaires for survey study

1. General Socio-demographic questions

Instruction: The following questions asks about your personal socio-demographic condition. Therefore, please provide the most appropriate personal answers for each question.

QNo	Question	Response option
1.1	Age	_____
1.2	Gender	1. Female 2. Male
1.3	Marital status	1. Single 2. In relationship 3. Married 4. Divorced/Widowed 5. Other_____
1.4	Religion	1. Orthodox Christian 2. Muslim 3. Protestant 4. Catholic 5. Other_____
1.5	Educational status	1. Illiterate 2. Completed elementary school 2. Completed high school 3. University diploma and above
1.6	How many children do you have?	1. None 2. One 3. Two 4. Three and more
1.7	How many children live in your household?	1. None 2. One 3. Two 4. Three and more
1.8	How many adults live in your household?	1. None 2. One 3. Two 4. Three and more
1.9	What is your role in the household?	1. Head of the household 2. Spouse of household head 3. Child of household head 4. Sibling of household head 5. Other _____
1.10	A. Employment status	1. Full time employed 2. Pare time employed 3. Self employed 4. Student 5. None employed 6. Other _____
	B. What is your main source of income?	1. Salary 2. Rental 3. Pension 4. Own business 5. No income 6. Other _____

	C. Is your income secured for the next 12 months?	1. Yes 2. No

2. Clinical questions

Instruction: The following questions asks about health-related condition. Therefore, please provide the most appropriate answer regarding your health-related condition for each question.

QNo	Question	Response option
2.1	Do you have any history of mental illness diagnosed by health professional in the last 12 months?	1. Yes 2. No
	A. What type of illness you have told by health professionals	1.Psychosis 2. Depressive disorder 3. Anxiety disorder 4. Other-specify
	B. What type of treatment you got?	1. Anti-psychotic 2. Anti-depressant 3. Anxiolytic 4. Other-specify
	C. For how long you took the treatment?	Specify-
	D. Do you still attend your psychiatric follow up regularly?	1. Yes 2. No
2.2	Did you attend another follow up in another place for your problem in the last 12 months?	1. Yes 2. No
2.3	Did you attend regular group sessions with peers for peer-support intervention in the last 12 months?	1. Yes 2. No
	A. If Yes, what type of group session?	1. HIV support group 2. Adherence group 3. Psychosocial counseling 4. Other _____
	B. If Yes, for how long	_____
	C. If Yes, how many group sessions you attended	_____

3. HRQOL (WHOQOL-HIV-Eth)

Instruction: the following questions are asking about your wellbeing and emotional state. From the given alternatives, choose the one which you are greed for.

QNo	Question	Response options				
3.1	How would you rate your quality of life in terms of social and economic?	1. Very poor	2. Poor	3. Neither poor nor good	4. Good	5. Very good
3.2	How satisfied are you with your health?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.3	In the past two weeks, to what extent do you feel that physical pain prevents you from doing what you need to do?	5. Not at all	4. A little	3. Moderate amount	2. Very much	1. Extremely
3.4	In the past two weeks, how much are you bothered by any physical problems related to your HIV infection?	5. Not at all	4. A little	3. Moderate amount	2. Very much	1. Extremely
3.5	In the past two weeks, how much do you need any medical treatment to function in your daily life?	5. Not at all	4. A little	3. A moderate amount	2. Very much	1. Extremely
3.6	In the past two weeks, how much do you enjoy life?	1. Not at all	2. A little	3. Moderate amount	4. Very much	5. Extremely
3.7	In the past two weeks, to what extent do you feel your life to be meaningful?	1. Not at all	2. A little	3. Moderate amount	4. Very much	5. Extremely
3.8	In the past two weeks, to what extent are you bothered by people blaming you for your HIV status?	5. Not at all	4. A little	3. Moderate amount	2. Very much	1. Extremely
3.9	In the past two weeks, how much do you fear the future?	5. Not at all	4. A little	3. A moderate amount	2. Very much	1. Extremely
3.10	In the past two weeks, how much do you worry about death?	5. Not at all	4. A little	3. A moderate amount	2. Very much	1. Extremely
3.11	In the past two weeks, how healthy is your physical environment?	1. Not at all	2. A little	3. Moderate amount	4. Very much	5. Extremely
3.12	In the past two weeks, do you have enough energy for everyday life?	1. Not at all	2. A little	3. Moderately	4. Mostly	5. Completely
3.13	In the past two weeks, how much worried are you about not being able to support your family?	5. Not at all	4. A little	3. Moderately	2. Mostly	1. Completely
3.14	In the past two weeks, to what extent do you have the opportunity for leisure activities?	1. Not at all	2. Little	3. Moderately	4. Mostly	5. Completely
3.15	In the past two weeks, how well are you able to get around?	1. Not at all	2. Little	3. Moderately	4. Mostly	5. Completely
3.16	In the past two weeks, how satisfied are you with your sleep?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.17	In the past two weeks, how satisfied are you with your ability to perform your daily living activities?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied

3.18	In the past two weeks, how satisfied are you with your capacity for work?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.19	In the past two weeks, how satisfied are you with yourself?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.20	In the past two weeks, how satisfied are you with your personal relationships?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.21	In the past two weeks, how satisfied are you with the support you get from your friends?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.22	In the past two weeks, how satisfied are you with the conditions of your living place?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.23	In the past two weeks, how satisfied are you with your access to health services?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.24	In the past two weeks, how satisfied are you with your transport?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.25	In the past two weeks, how satisfied are you with your relations to other people in your community?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.26	In the past two weeks, how satisfied are you with your access to adequate food and nutrition?	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
3.27	In the past two weeks, how often do you have negative feelings such as blue mood, despair, anxiety, depression?	5. Never	4. Seldom	3. Quite often	2. Very often	1. Always

4. Patient Heath Questionnaire Depression Module (PHQ-9)

During the last two weeks, how often have you been bothered by any of the following problems?

(Interviewers: Please repeat response options for each of the following questions).

		Not at all	Several days	More than half the days	Nearly every day
4.1	Little interest or pleasure in doing things	0	1	2	3
4.2	Feeling down, depressed, or hopeless	0	1	2	3
4.3	Trouble falling or staying sleep, or sleeping too much	0	1	2	3
4.4	Feeling tired or having little energy	0	1	2	3
4.5	Poor appetite or eating too much	0	1	2	3
4.6	Feeling bad about yourself - or that you're a failure or have let yourself or your family down	0	1	2	3
4.7	Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
4.8	Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
4.9	Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

		Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
4.10	How difficult have these problems made it for you to do your work, take care of things at home, take care of yourself, or get along with other people?	0	1	2	3

5. MINI Depression module

		No	Yes
A1a	Were you ever depressed or down, or did you feel sad, empty or worthless, most of the day, nearly every day, for two weeks?	0	1
A1b	For the past two weeks, were you depressed or down, or did you feel sad, empty or hopeless, most of the day, nearly every day?	0	1
A2a	Were you ever much less interested in most things or much less able to enjoy the things you used to enjoy most of the time, for two weeks?	0	1
A2b	In the past two weeks, were you much less interested in most things or much less able to enjoy the things you used to enjoy, most of the time?	0	1
A3	Over that two-week period, when you felt depressed or uninterested?	0	1
A3a	Was your appetite decreased or increased nearly every day? Did your weight decrease or increase without trying intentionally (by ±5% of body weight or ± 3.5kg for 70 kg person in a month)?	0	1
A3b	Did you have trouble sleeping nearly every night over the past 2-week period (Difficulty falling asleep, waking in the middle of the night, early morning wakening or sleeping excessively)?	0	1
A3c	Did you talk or move more slowly than normal or were you fidgety, restless or having trouble sitting still almost every day over the past 2-week period? Did anyone notice this?	0	1
A3d	Did you feel tired or without energy almost every day over the past 2-week period?	0	1
A3e	Did you feel worthless or guilty almost every day over the past 2-week period?	0	1
A3f	Did you have difficulty concentrating or making decisions almost every day over the past 2-week period?	0	1
A3g	Did you repeatedly consider hurting yourself, feel suicidal, or wish that you were dead over the past 2-week period? Did you attempt suicide or plan a suicide?	0	1
A3h	Did you feel irritable?	0	1
A4	Did these symptoms cause significant distress or problems at home, at work, socially, in your relationships, at school or in some other important way, and are they a change from your previous functioning over the past 2-week period?	0	1
A5	In between 2 episodes of depression, did you ever have an interval of at least 2 months, without any significant depression or any significant loss of interest?	0	1
A6	How many episodes of depression did you have in your life time? (between each episode there must be at least 2 months without any significant depression)	0	1

B	In the past month did you,		
B1	In the past month did you think that you would be better off dead or wish you were dead?	No	Yes
B2	In the past month did you want to harm yourself?	No	Yes
B3	In the past month did you think about suicide?	No	Yes
B4	In the past month did you have a suicide plan?	No	Yes
B5	In the past month did you attempt suicide?	No	Yes
B6	In your life time, did you ever make a suicide attempt?	No	Yes
	Is at least 1 of the above coded yes?	No	Yes
	If yes, specify the level of suicide risk as follows; C1 or C2 or C6 = YES, indicates LOW suicide risk C3 or (C2+C6) = YES, indicates MODERATE suicide risk C4 or C5 or (C3 + C6) = YES, indicates HIGH suicide risk		

6. WHODAS 12 item questions

In the past 30 days, how much difficulty did you have in:						
QNo	**Question**	**None**	**Mild**	**Moderate**	**Severe**	**Extreme**
6.1	Standing for long periods such as 30 minutes?	5	4	3	2	1
6.2	Taking care of your household responsibilities?	5	4	3	2	1
6.3	Learning a new task, for example, learning how to get to a new place?	5	4	3	2	1
6.4	How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	5	4	3	2	1
6.5	How much have you been emotionally affected by your health problems?	5	4	3	2	1
6.6	Concentrating on doing something for ten minutes?	5	4	3	2	1
6.7	Walking a long distance such as a kilometre [or equivalent]?	5	4	3	2	1
6.8	Washing your whole body?	5	4	3	2	1
6.9	Getting dressed?	5	4	3	2	1
6.10	Dealing with people you do not know?	5	4	3	2	1
6.11	Maintaining a friendship?	5	4	3	2	1
6.12	Your day-to-day work?	5	4	3	2	1

6.13	Overall, in the past 30 days, how many days were these difficulties present?	
6.14	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	
6.15	In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	

7. Perceived social support

Circle “1” if very strongly disagree

Circle “2” if strongly disagree

Circle “3” if mildly disagree

Circle “4” if neutral

Circle “5” if mildly agree

Circle “6” if strongly agree

Circle “7” if very strongly agree

7.1	There is a special person who is around when I am in need.	1	2	3	4	5	6	7
7.2	There is a special person with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
7.3	My family really tries to help me.	1	2	3	4	5	6	7
7.4	I get the emotional help and support I need from my family.	1	2	3	4	5	6	7
7.5	I have a special person who is a real source of comfort to me.	1	2	3	4	5	6	7
7.6	My friends really try to help me.	1	2	3	4	5	6	7
7.7	I can count on my friends when things go wrong.	1	2	3	4	5	6	7
7.8	I can talk about my problems with my family.	1	2	3	4	5	6	7
7.9	I have friends with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
7.10	There is a special person in my life who cares about my feelings.	1	2	3	4	5	6	7
7.11	My family is willing to help me make decisions.	1	2	3	4	5	6	7
7.12	I can talk about my problems with my friends.	1	2	3	4	5	6	7

8. The following questions were used to collect clinical data from clients’ medical record review

8.1	A. When the diagnosis of HIV/AIDS done?	_____
	B. When clinical follow up started?	_____
	C. When ART treatment initiated?	_____
	D. For how long s/he has been taking ART treatment?	_____
	E. Total Number of medications s/he is taking	_____
8.2	Does s/he experience medication side effect?	1. Yes 2. No
	If yes, what side effect?	_____
	If yes, severity of the side effect	1. Low 2. Medium 3. Moderate 4. Severe
8.3	Does s/he attend her/his follow up regularly?	1. Yes 2. No
	If No, what was the reason mention over the chart?	_____
8.4	Is there other illness/disease s/he diagnosed in the last 12moths other than HIV/AIDS	1. Yes 2. No
	If Yes, mention	_____
	What treatment s/he is getting?	_____
8.5	A. Current CD4 count	_____
	B. Last CD4 count	_____
	C. Date last CD4 count done	_____
8.6	A. Current viral load count	_____
	B. Last viral load count	_____
	C. Date last viral load done	_____
8.7	WHO disease stage	_____
8.8	ART treatment regimen	_____
8.9	Did the client has taken the prescribed medications correctly since the last follow up?	1. Yes 2. No
8.10	If No for Q9.9, how money times medications are skipped?	_____

Module two: Interview guide for adaptation of group IPT

Interview guide for people living with HIV/AIDS (PWHA), case managers and adherence supporters

Objective of questionnaire: Section one aimed to explore conceptualization of depressive symptoms by People Living with HIV/AIDS (PWHA) and adherence counsellors who are attending their clinical follow up in the ART clinic in Felegehiwot Hospital. Section B aimed to identify preferred treatment strategy to help depressed PWHA in Felegehiwot referral hospital.

Section A. Exploring depression using explanatory model of illness among PLWHA.

Let's listen a case presentation about stories of Selam then we will discuss about her story later (the case will be displayed on a projector). After listening the stories of Selam ("*Now, let's discuss how you understood Selam's story*").

1. Can you explain to me what Selam's problems are? (*Probe* for understanding e.g., is it understood as witchcraft, stress etc, if it is any of these things, how do they work eg how does the witchcraft work, how does the stress work?, etc).

2. What are the different words that you and other people use to describe Selam's problem? *Probing* (What other symptoms do people have who are depressed and how do these symptoms affect her life? How long do these symptoms usually last?)

3. What do you think causes these feelings? (For example, is it specific events or situations that trigger or start the symptoms, or is it people's beliefs, or other things)

4. How common are depressive symptoms in PWHA? Are PWHA more likely to be depressed than other people? If so, why?

5. Where do they seek help?

Section B. Exploring treatment preferences using ecological validity and culture sensitivity model

1. What are the best treatment options available to help depressed PWHA in Felegehiwot hospital?
2. What additional support do you think they need?
3. What do you know about psychological treatments?

Now let me tell you about Group Interpersonal Therapy (Group IPT). Group IPT is one of psychological treatments used to treat depressive symptoms. It focuses to alleviate depressive symptoms triggered by one or more of these four problems: 1) grief/loss of beloved one's, 2) Dispute/disagreement, 3) Life change including divorce, separation, migration, job loss, and 4) loneliness/separation. Depressed people will meet in group to share their personal problems that are causing their depressive symptoms, to share coping skills and to set goals to solve difficult situations. Therefore, depressive symptoms can be treated when those triggering factors solved using Group IPT.

Based on the above description of Group IPT, let's discuss the following ideas.

4. Do you know about it before and if yes what are your thoughts about expanding it for larger population Ethiopia?
    - Think of its acceptability and appropriateness.

- Is it feasible in this context and if not, how can we make it feasible?

You've told me about what types of treatments you think may work for PWHA with depressive symptoms. Let's talk about how the treatment should be provided. For example, who should provide it, where it should take place, how often, and so on.

Probes:

- What time of day and week
- Where?
- How long the sessions should be and how many sessions
- Who should conduct the therapy as counselor? (gender, age, qualification, locality, relationship/ community relations).
- Group or individual

Let's think about any problems in running such therapy sessions.

Probes:

- What would make it acceptable to people
- Would it be convenient for people?
- How can any problems be overcome?

Section C. Case vignette

Selam is 30 years old housewife. She has been feeling unusually sad and miserable for the last few weeks. She has lost interest in everything and she is not getting pleasure at all. Even though she feels tired all the time, she has trouble sleeping nearly every night. Selam does not feel like eating and has lost weight. She cannot keep her mind on housework and puts off making decisions. Even day-to-day tasks seem too much for her such as cooking, baking, house cleaning and other activities. Once she told her husband that she is feeling helpless, hopeless, guilty with unknown reasons so that she prefers to die in whatever means. This has come to the attention of her husband who is concerned about Selam's death wish.

Module three: Fidelity assessment checklists

The following questions were used to assess fidelity of group IPT intervention.

Note: These forms can be used as a reminder of the different tasks to complete in each session, as a self-assessment tool for facilitators or by peers or a supervisor as part of ongoing learning and supervision.

3.1. Pre-group phase (Individual session)

Group member ID: _____

Session # and date: _____

Facilitators Name: _____

Supervisors Name: _____

( ) Audio ( ) Live supervision ( ) Verbal report only

Please rate using the following key terms:

Superior	Satisfactory	Needs improvement	Failed to attempt	Not applicable to session	Couldn't assess in supervision
1	2	3	4	5	6

Introduces self and project to person	1	2	3	4	5	6
Reviews person's depression symptoms by administering a depression rating scale	1	2	3	4	5	6
Explains that depression is a common but very impairing condition and discusses person's impairment	1	2	3	4	5	6
Gives hope that depression is treatable	1	2	3	4	5	6
Assigns person the sick role	1	2	3	4	5	6
Links beginning of depression to interpersonal problem(s)	1	2	3	4	5	6
Conducts interpersonal inventory	1	2	3	4	5	6
Selects and agrees with the person on 1 or 2 IPT problem areas	1	2	3	4	5	6
Agrees with person on interpersonal goals	1	2	3	4	5	6
Discusses number of sessions, attendance and group rule	1	2	3	4	5	6
Demonstrates knowledge of Group IPT model	1	2	3	4	5	6
Works at establishing a good relationship with prospective group member	1	2	3	4	5	6
Demonstrates good understanding of person's problem and its context	1	2	3	4	5	6
Has a collaborative style	1	2	3	4	5	6

Individual session: supervisor's recommendations to facilitator: _____

Strengths: _____

Difficulties: _____

Plans for improvement (rehearse, assign reading, etc.):

_____

3.2. Initial group phase (Group session 1)

Group ID: _____

Session # and date: _____

Facilitator: _____

Supervisor: _____

( ) Audio ( ) Live supervision ( ) Verbal report only

Please rate using the following key:

Superior	Satisfactory	Needs improvement	Failed to attempt	Not applicable	Couldn't assess in supervision
1	2	3	4	5	6

Introduces self and project to group	1	2	3	4	5	6
Conducts group icebreaker activities (each member introduces the person next to them, etc.)	1	2	3	4	5	6
Discusses purpose of the group	1	2	3	4	5	6
Explains that depression is a common but very impairing condition, and asks each person about impairment, while removing guilt	1	2	3	4	5	6
Encourages each group member to talk about depression symptoms, related life problems and goals	1	2	3	4	5	6
Outlines group rules (confidentiality, attendance, etc.)	1	2	3	4	5	6
Demonstrates knowledge of Group IPT model	1	2	3	4	5	6
Works at establishing rapport and group cohesion	1	2	3	4	5	6
Shares time fairly amongst group members	1	2	3	4	5	6
Is able to keep group focused	1	2	3	4	5	6

Session 1: Supervisor's recommendations to facilitator: _____

Strengths: _____

Difficulties: _____

Plans for improvement (rehearse, assign reading, etc.):

_____

3.3. Middle group phase (group sessions 2–7)

Group ID: _____ Session # and date: _____ Facilitator: _____

Supervisor: _____

( ) Audio ( ) Live supervision ( ) Verbal report only

Please rate using the following key:

Superior	Satisfactory	Needs improvement	Failed to attempt	Not applicable to session	Couldn't assess in supervision
1	2	3	4	5	6

Welcomes group, reviews each member's depression symptoms for past week with the depression rating scale and obtains depression score	1	2	3	4	5	6
Comments on improvement or worsening of depression and gives each group member hope	1	2	3	4	5	6
Connects improvement or worsening of depression to past week's interpersonal events and links these events to the IPT problem area(s)	1	2	3	4	5	6
Focuses on each group member's identified IPT problem area(s)	1	2	3	4	5	6
When group member deals with grief, facilitator enables discussion of the circumstances of the loss	1	2	3	4	5	6
When group member deals with grief, facilitator reviews their relationship with the deceased person	1	2	3	4	5	6
When group member deals with grief, facilitator helps with reconnection with the world and future plans	1	2	3	4	5	6
When group member discusses disputes, facilitator clarifies their expectations about the situation that triggered dispute	1	2	3	4	5	6
When group member discusses disputes, facilitator identifies problematic communications	1	2	3	4	5	6
When group member discusses life changes, facilitator helps them find positives and negatives about old role	1	2	3	4	5	6
When group member discusses life changes, facilitator helps them find positives and negatives or opportunities in the new role	1	2	3	4	5	6
When group member discusses life changes, facilitator helps them develop skills to better manage the new role	1	2	3	4	5	6
When group member is socially isolated, facilitator helps them to acquire skills to engage in social interactions	1	2	3	4	5	6
Analyses interpersonal situations in detail to find out what happened (communication analysis)	1	2	3	4	5	6
Helps group members practise new communication strategies	1	2	3	4	5	6
Encourages group members to help each other to generate options to deal with problems	1	2	3	4	5	6
When group members have no options, facilitator encourages them to find advocates and others with more power to help	1	2	3	4	5	6
Encourages group members to use role-play to rehearse desirable interactions	1	2	3	4	5	6
Demonstrates knowledge of Group IPT model	1	2	3	4	5	6
Works at establishing good relationships and group cohesion	1	2	3	4	5	6
Shares time fairly amongst group members	1	2	3	4	5	6
Is able to keep group focused	1	2	3	4	5	6

Sessions 2–7 Supervisor's recommendations to facilitator: _____

Strengths: _____

Difficulties: _____

Plans for improvement (rehearse, assign reading, etc.) _____

3.4. Termination group phase (group session 8)

Group ID: _____

Session # and date: _____

Facilitator: _____

Supervisor: _____

( ) Audio ( ) Live supervision ( ) Verbal report only

Please rate using the following key:

Superior	Satisfactory	Needs improvement	Failed to attempt	Not applicable to session	Couldn't assess in supervision
1	2	3	4	5	6

Reviews each group member's depression from start of the treatment to now and comments on progress	1	2	3	4	5	6
Discusses warning symptoms of depression (How would you know that you are getting depressed again?)	1	2	3	4	5	6
Identifies successful strategies used in treatment	1	2	3	4	5	6
Reviews group members' interpersonal goals, successes and efforts to change	1	2	3	4	5	6
Discusses generalization of strategies to future situations for group members	1	2	3	4	5	6
Discusses his/her own and group members' feelings about ending treatment	1	2	3	4	5	6
Assesses need for further treatment	1	2	3	4	5	6
Discusses possibility of recurrence of depression and plan for managing recurrence	1	2	3	4	5	6
Demonstrates knowledge of Group IPT model	1	2	3	4	5	6
Works at maintaining relationships with and amongst group members	1	2	3	4	5	6
Shares time fairly amongst group members	1	2	3	4	5	6
Is able to keep group focused	1	2	3	4	5	6

Module four: Intervention evaluation checklist

Intervention evaluation questions adapted from *Sibeko et al…2018.*

	Not applicable	Strongly disagree	Disagree	Cannot decide	Agree	Strongly agree
All information discussed was relevant to me.	1	2	3	4	5	6
The sessions were long enough to discuss topics.	1	2	3	4	5	6
I was feeling comfortable with sessions.	1	2	3	4	5	6
Chances were provided for me to ask questions.	1	2	3	4	5	6
Discussion point were easy to understand.	1	2	3	4	5	6
I feel relaxed and ready to listen and to talk.	1	2	3	4	5	6
The sessions helped me to work on my problems.	1	2	3	4	5	6
The homework helped me to solve my problems.	1	2	3	4	5	6
The facilitator was prepared for the sessions.	1	2	3	4	5	6
The facilitators know the content of the intervention.	1	2	3	4	5	6
The facilitators were good at managing the group.	1	2	3	4	5	6
The facilitator made the sessions interesting.	1	2	3	4	5	6
The facilitators communicate clearly.	1	2	3	4	5	6
The facilitators encourage participation.	1	2	3	4	5	6
The facilitation space was suitable for group session.	1	2	3	4	5	6
The session location was easy to find	1	2	3	4	5	6
I need such intervention for others too.	1	2	3	4	5	6
The intervention was relevant to manage my problems.	1	2	3	4	5	6
The experience I found from others helped me to resolve my problems.	1	2	3	4	5	6
I am satisfied with the intervention	1	2	3	4	5	6
I am satisfied with the facilitator	1	2	3	4	5	6
I am satisfied with the group session	1	2	3	4	5	6
Additional comments _____ _____						

Module five: Group IPT competency assessment for counsellors

Counsellors competence for group IPT was assessed at the completion of the training using the following questions.

1. Please name the four types of triggers of depression in IPT define each one.

2. What are the phases of Group IPT? (Just mention them.)

3. Describe the tasks that need to take place in the pre-group phase.

4. Describe the goals and steps of the initial group phase.

5. Describe how a typical session starts in the middle phase.

6. In the middle phase, what are the strategies for working with grief?

7. What are the stages of a dispute? (Please describe each.)

8. What are the strategies for managing disputes?

9. What are the strategies for life changes?

10. What are the strategies for loneliness/social isolation?

11. What is communication analysis? Can you give an example?

12. Describe 2 other techniques that you use in Group IPT (across strategies). Please explain.

13. Describe 1 way to involve group members in group discussions, and give examples.

14. What is something you can do to distribute your time fairly among the group members?

15. What happens during the termination phase?

Note: Test scoring instructions are as follows: every question gets 2 points if answered adequately, 1 point if something important is missing and 0 points if the answer is incorrect. Usually the facilitator should be able to answer 70% of the 15 questions correctly (21 points).

Appendix E. **Sample of consent forms**

Alan J. Flisher Centre for Public Mental Health
Department of Psychiatry and Mental Health
University of Cape Town
46 Sawkins Road, Rondebosch, 7700
Cape Town, South Africa
Tel. +27 21 685 0120
Fax +27 21 685 1223

Informed consent form for survey of quality of life, depressive symptoms and ART adherence status – Survey in Objective 2.

This informed consent is for people with HIV/AIDS in a research titled “Depression and HIV/AIDS: adapting and piloting group interpersonal therapy for treatment of depressive symptoms among people with HIV/AIDS in Northwest Ethiopia”

Hello. My name is Biksegn Asrat. I am an AMARI PhD fellow at the Alan J. Flisher Centre for Public Mental Health in the University of Cape Town, South Africa. You are being asked to participate in an interview as part of a study that I am conducting. Before you agree to take part, you should understand what it involves. This letter is to help you decide if you want to participate in this study. Participation is voluntary, and you should agree to take part only if you are happy with all it entails.

The overall aim of this research project is to explore the problems that people living with HIV/AIDS are facing, and to identify clients who have depressive symptoms. Later part of the study aimed to treat depressive symptoms using group interpersonal therapy. Depressive symptoms and not taking ART medications are affecting the wellbeing of many people with HIV/AIDS. Therefore, interventions are needed to treat depressive symptoms and to promote ART medication adherence.

The objective of this interview is to identify people who have depressive symptoms among ART follow up clients at Bahir Dar Felegehiwot referral hospital. You have been approached to participate in this study because you are one of the clients attending ART follow up at Bahir Dar Felegehiwot referral hospital. The interview will help us to generate evidence and you will know your mental health status at the end of the interview. Your usual HIV care will not be negatively impacted in any way if you choose not to participate in the study.

What is being asked of you?

If you agree to take part in this study, you will be one of 395 clients participating. You will be asked to give answers for prepared structured questions about your background, general health and emotional /or

psychological status. You also will be asked about your social support status, your ART follow up status, and your habits. The interview could take 30 to 45 minutes. Additionally, I need to know your previous CD4 count, viral load and other medical information. Therefore, if you agree for the interview, then I will look at your medical record to see your previous general health status. The information that you provide will help me to know whether you need treatment or not. Furthermore, it will allow me to know what is really affecting the wellbeing of your mental health.

Potential risks and discomforts of participating in this study

There is only minimal risk to participating in this survey study. There are two anticipated potential risks for participants: (1) improper disclosure of confidential information; and (2) unpleasant feeling associated with issues raised during the interview. There is a risk of leaking confidential information out of the group members. However, the probability of improper disclosure of confidentiality by research staffs is low because all the research staffs received intensive training about how to handle confidentiality. In addition, your name will not be written in the questionnaire, and the data will be accessed by the principal investigator only. As mentioned above, some questions may provoke unpleasant feeling, but you will not be pressured to give answer for such questions. You can ask the data collector to skip the specific question that has high discomfort for you.

Potential benefits of participating in this study

Your participation in the study will help you to know your mental health status such as: presence of depressive symptoms, the quality of your living standard, your social relationship and the status of your social support. Once after you understood your mental health status, then I will assist you what kind of treatment you should get. If you are identified having depressive symptoms you will have a chance to get free psychological treatment from us. If you have severe form of depression, then I will refer you to a specialized care. Otherwise, there is no available fund to be paid for your participation in this interview.

Confidentiality and privacy

All study staffs will receive intensive training in participants confidentiality procedures and there are serious sanctions (including dismissal) if confidentiality is broken. Any information that you will give me will remain confidential. The questionnaire and the informed consent is labelled by secret numbers (codes). You will be asked to put your name and signature on the informed consent only. The questionnaire will not have your name and it will be stored in a locked cabinet which is accessed by the primary researcher only. The data will be entered into a computer software and it will be saved in a password secured folder on the primary researchers' computer. The questionnaire and the consent form will be destroyed within 2 years after the compilation of this study. The University of Cape Town (UCT) Human Research Ethics committee (HREC) will however have access to all data. We will use the information you provide us to write and publish papers in academic journals, but this data will not be identified by name. Your name will not appear

anywhere in any published material and your identity will remain anonymous as codes will be used. However, confidentiality will need to be broken if you pose a danger to yourself or others.

Rights of participants

Your participation is entirely voluntary and there is no penalty for refusing to participate. If you decided to participate, you may choose to stop your participation at any time. You are free not to provide answer for specific questions. There will be no consequence at all. However, your participation is highly needed for this research project. You have the right to know how confidentiality will be maintained. If you believe confidentiality will be broken, then you can leave from participation at any time. This study will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki.

Who is funding the study?

The study is being conducted through the Alan J. Flisher centre for Public Mental Health (UCT) and the African Mental Health Research Initiative (AMARI). It is funded by AMARI consortium whose overall goal is to build and support research in mental, neurological and substance use in Africa. For more information you can visit: https://amari-africa.org/biksegn-asrat/

Reimbursement

There is no reimbursement for this interview. However, refreshment will be provided at the end of the interview.

Who to contact with question

If you have any questions, concerns or complaints about your rights as a participant, please contact **Biksegn Asrat** at any time using the following addresses. He is available on (+251) 923229274 in Ethiopia, (+277) 30544676 in South Africa or via email biksegnasrat1@gmail.com or ASRBIK001@myuct.ac.za

Country supervisor of this study is **Dr Fentie Ambaw**. Therefore, you can call him through his address whenever you have complaints. Mobile: (+251) 911 81 70 07, Office: (+251) 588 209834, E-mail: fentiea.getahun@gmail.com / fentiea@bdu.edu.et
The primary supervisor of this research is **Associate Prof Marguerite Schnider**, Office: +27 21 406 6308; Cell: +27 73 253 5080, email work: marguerite.schneider@uct.ac.za Skype: marguerite8242. You are welcome to contact her if you have any additional queries.

If you have any concerns or complaints please you can call the chairperson of the HREC, **Prof Marc Blockman** on (021) 4066496, UCT, South Africa, email: marc.blockman@uct.ac.za

Indicating consent

Please let us know if you have any questions before checking this consent form. Please check each item to show that you agree to what is required (leave blank if you do not agree):

Agree	
	I agree to take part in the interview which has been fully explained to me.
	I understand that my participation in this interview is completely voluntary, and there will be no penalty if I choose not to participate.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this study. You will receive a copy of this signed consent form.

Participants (Name and signature) Date

Person obtaining consent (signature and printed Name) Date

Witness (signature and printed Name) Date

*A witness is required if the research participant cannot read (e.g. blind or illiterate) or if it is required by the study plan. The witness should participate in all of the discussions with regards to the participant research during the consent process. By signing this consent form, the witness guarantees that all the information with in the consent has been explained to the participant, and that the consent seemed to have been understood and given by free will.

Appendix F. Standard operating procedure (SOP)

Step 1: Checking eligibility of participants for the study

Step2: Informed consent administration

Step 3: Interviewing

Step 4: Score PHQ-9 (Case if ≥5 or None if <4)

Step 5: Refer participants with PHQ score of ≥5 to the intervention facilitators (counsellors)

Step 6: Facilitators will invite the participant for group IPT after individual counselling session

Step 7: Informed consent administration for group IPT intervention

Step 8: Check suicide risk

Step 9: Refer if there is suicidal or homicidal behaviour

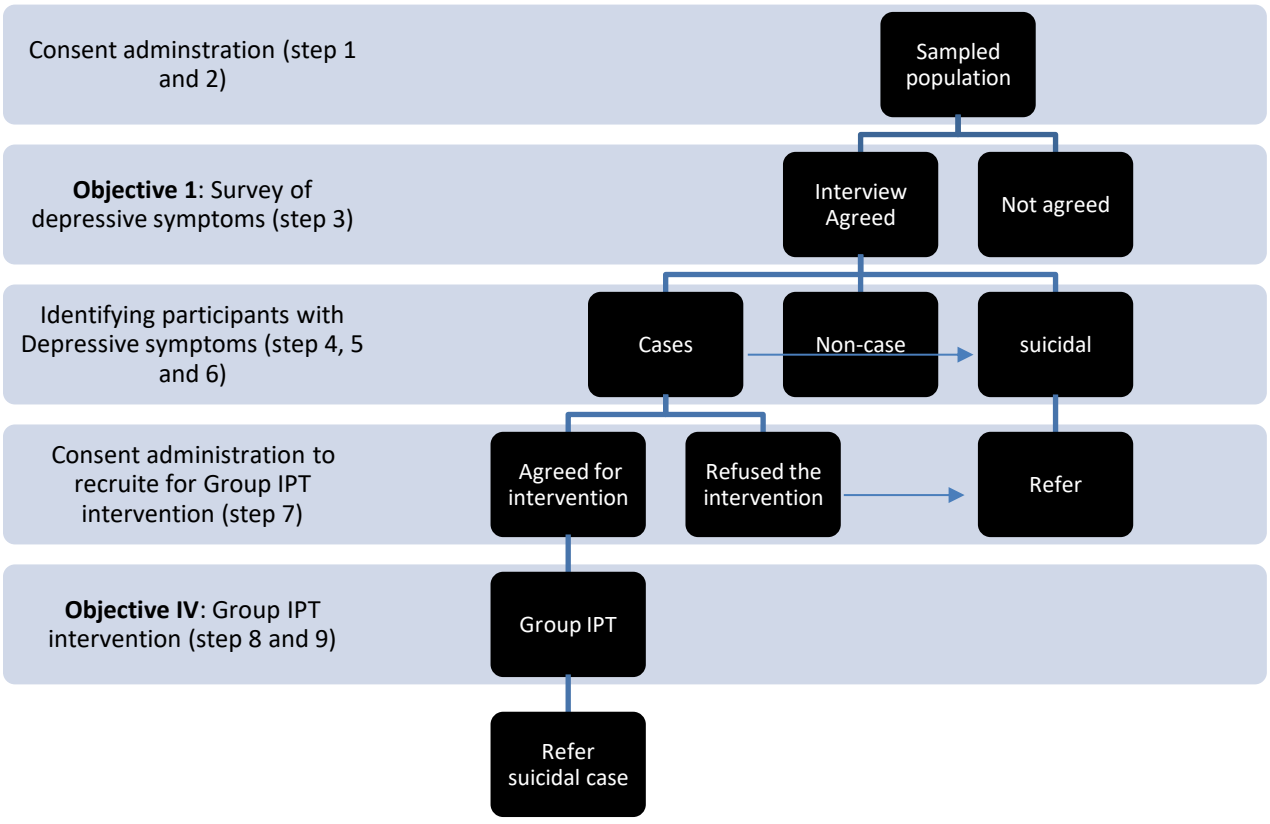

Figure 17. Diagrammatical illustration of the standard operating procedure that used in the recruitment of participants into the intervention

Appendix G. Stepwise adaptation framework for the WHO group IPT manual

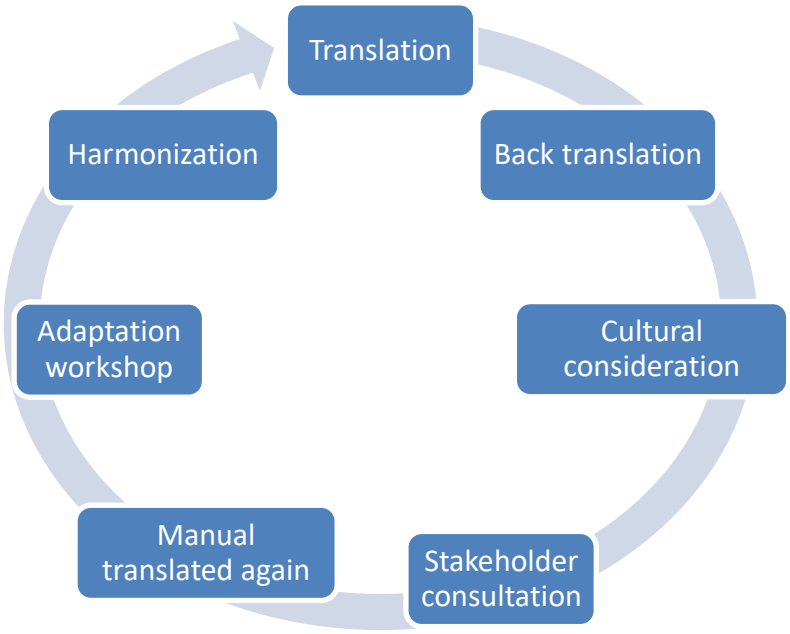

Figure 18. Participatory and Iterative Process Framework for Language Adaptation (PIPFLA) that used to translate and adapt the WHO group IPT manual

Appendix H. Counsellors weekly notes sample form

Group members name: _____
Counsellors name: _____
Group number: _____

Date: _____
Depression score at baseline: _____

Note including progress on IPT problem areas:

Plan for next week (including goals):

Homework: